The 'Retention in Randomised Control Trials (RRCT)' Project

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Declaration

This thesis is the result of my own work. Material from the published or unpublished work of others, which is referred to in this thesis, is credited to the appropriate author in the text.

I declare that the work in this thesis conforms to Durham University's Core Regulations for Research Degrees by thesis.

I have not distributed any part of this thesis for any other degree or to any other university for examination either in the United Kingdom or overseas.

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Abstract

The Retention in Randomised Control Trials (RRCT) project assessed whether a high retention rate could be achieved in a longitudinal Randomised Control Trial (RCT) - The North-East Cot (NECOT) trial - by implementing various interventions: a relationship based intervention, a combination of interventions (relationship and prepaid incentive), a prepaid incentive intervention and a free sample/prize intervention. The RRCT project used a subset of participants (*n*=450) from the NECOT trial who were allocated consecutively to one of six groups (two control groups and four intervention groups).

None of the interventions tested had a significant impact on reducing attrition above the normal protocol of the NECOT trial. The relationship based intervention had significantly higher attrition, thus a negative effect, compared to control group 1 (χ^2 =7.860, df =1 and p =0.005), control group 2 (χ^2 =6.182, df =1 and p =0.013) and the control groups combined (χ^2 =9.587, df =1 and p =0.002).

Women who were aged below 25, living without a partner/husband, up to university educated or with a household income up to £20,000 were significantly more likely to drop out of the NECOT trial. Also, women aged below 25, living without a partner/husband, of 'other' ethnicity or with a household income up to £20,000 responded best to the prepaid intervention.

The RRCT project provides an anthropological approach to attrition and retention thus contributing to the literature on this subject. Both social and biological anthropological perspectives can be applied to reasons for retention and attrition, for instance Prisoner's Dilemma, Tit-For-Tat strategy, reciprocal altruism, moral motivation, reciprocity and building social obligations.

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Chapter 1: Introduction

The Retention in Randomised Control Trials (RRCT) project assessed whether a high retention rate could be achieved in a longitudinal Randomised Control Trial (RCT) - the North-East Cot (NECOT) trial - by implementing various interventions. The intervention types used in the RRCT project had been implemented as means of reducing attrition in other studies and were introduced to the RRCT project to test the effect on retention of providing the following to NECOT participants: a) regular contact, b) regular incentives, c) a combination of interventions and d) a prepaid incentive. These interventions were applied to consecutive and mutually exclusive groups of participants to ascertain what would be most effective in preventing attrition in the NECOT trial. The interventions were selected based upon the theoretical considerations of game theory, reciprocal altruism, reciprocity, and moral and social obligation.

As a RCT is the preferred methodology for conducting research which aims to inform clinical practice or social policy (Schwartz and Lellouch 1967 cited Treweek and Zwarenstein 2009:2), it is necessary to have a high retention rate and thus low attrition to ensure enough data to give the statistical analyses sufficient power (Friedman *et al*. 1998). Many studies have assessed aspects of retention and attrition in clinical trials and although research has highlighted factors influencing participation in RCTs such as 'the greater good' (e.g., Dixon-Woods and Tarrant 2009; Aitken *et al*. 2003; Sammons *et al*. 2007; Hayman *et al*. 2001; Janson *et al*. 2001), 'personal relevance/benefit' (e.g., Sammons *et al*. 2007; Gross *et al*. 2001; Kerr *et al*. 2006) and 'risk perception' (e.g., Maayan-Metzger *et al*. 2008; Tait *et al*. 2003), an anthropological approach has not yet been applied.

The RRCT project addressed whether certain aspects of anthropological theory might be useful in explaining reasons for retention and attrition in RCTs and thus if applied could reduce trial attrition. Both biological and social theories were considered and the RRCT project focussed on the following: game theory (in particular Prisoner's Dilemma, Tit-for-Tat and Free Riders), moral motivation, reciprocal altruism, building social obligations and reciprocity. Game theory (Axelrod and Hamilton 1981; Hargreaves Heap and Varoufakis 2004) and

reciprocal altruism (Trivers 1971) can give insight into how our evolutionary psychology shapes our behaviour and decision making; considering social theories such as building social obligations (Mauss [1925] 1967) and reciprocity (Sahlins 1972) provides an understanding of how our social obligations can have an impact on our behaviour and decision making. Therefore, if we can understand what mechanisms are guiding our behaviour and decision making, then researchers could design RCTs to take these mechanisms into account, which in turn could reduce attrition from RCTs.

The RRCT project used a subset of participants (*n*=450) from the North-East Cot (NECOT) trial. The NECOT trial is a longitudinal RCT with 1230 participants being conducted at the Royal Victoria Infirmary (RVI) hospital, Newcastle-upon-Tyne to assess the effect that two different cot types -- a standalone cot (normal procedure) or a side-car crib (intervention) -- used on the postnatal ward for newborn babies, may have on breastfeeding and bed-sharing practices of mother and infant in the first six months after delivery. The NECOT trial commenced in October 2007 and is due to complete in March 2010. Participants are randomly assigned to a cot type via a computerised programme, and when mother and baby return home mothers are asked to ring an automated telephone system (free-phone number) to answer a set of questions regarding infant sleep and feeding practices on a weekly basis for 26 weeks. This provides the data required to assess the effect of the two cot types on infant sleep and feeding practices amongst this sample of the population of the North-East of England. A preliminary study into proximity performed at the RVI by Ball *et al*. (2006) formed the basis of the NECOT trial.

In brief, the first 450 participants recruited for the NECOT trial were subsequently allocated to one of six groups (two control groups and four intervention groups) for the RRCT project. All six groups were subjected to the normal recruitment process adopted by the NECOT trial (discussed in Chapter 3). The first and sixth groups were control groups. The first intervention group received a relationship based intervention (testing relationship based interventions), the second intervention group received a relationship based intervention and a prepaid incentive (testing a combination of interventions), the third intervention group received a single prepaid

incentive (testing prepaid incentives alone), and the fourth intervention group received a regular non-monetary incentive (testing gift incentives).

This chapter has provided a brief overview of the RRCT project and why it has been conducted. Chapter 2 provides a review of the literature where I will explore: evidence-based medicine and RCTs, why people enrol in RCTs, participant loss in RCTs, anthropological perspectives on trial participation and retention, practical interventions implemented to reduce trial attrition, and application of anthropological theories. I then pose the hypotheses that are tested in the RRCT project. Chapter 3 is the methodology section and details: what part the RRCT project plays in the NECOT trial, the normal process of the NECOT trial, the content of the interventions used in the RRCT project, the allocation of participants to a RRCT project intervention group or control group, ethical issues, terminology used and the type of analyses that were performed on the results. Chapter 4 provides the results of the various hypotheses testing and exploratory analyses. In Chapter 5 I discuss the results in detail and propose an anthropological explanation for the results obtained. I also make further recommendations for future research that arises from the RRCT project. Chapter 6 provides a conclusion to this piece of research.

Chapter 2: Literature Review

2.1 Evidence-based medicine and Randomised Control Trials

Sackett *et al*. (2000:1) state that evidence-based medicine is "the integration of best research evidence with clinical expertise and patient values" and that the research has to be clinically relevant whilst utilising the knowledge and skills of clinicians and considering the individual needs of patients. For new interventions to be implemented by the National Health Service in the United Kingdom, they need to have undergone a clinical trial preferably a Randomised Control Trial (RCT) (Kerr *et al*. 2006). RCTs are considered to be the gold standard research method used in evidence-based medicine (Torgerson and Torgerson 2008) - gold standard being the term given in medicine for definitive and decisive standards and is thus the 'measuring stick' by which clinical practices are gauged (Timmermans and Berg 2003). Evidence-based medicine therefore employs scientific evidence to form guidelines used in clinical practice (*ibid*.).

2.1.1 The conduct of Randomised Control Trials

RCTs have been conducted for social intervention studies since the 1920s/1930s (Torgerson and Torgerson 2008), although clinical trials date back to the 18th century (Friedman *et al*. 1998). For example Lind (1753 cited in Pocock 2000:14) performed a RCT in the 1700s on 12 scurvy sufferers on board the *Salisbury*; by testing six different treatments he concluded that providing the patients with oranges and lemons would clear the infection. A RCT therefore is where a new treatment is trialled on a group of humans (Matthews 2000), and aims to establish whether a tested intervention is more beneficial than the 'normal' practice (Friedman *et al*. 1998; Torgerson and Torgerson 2008). Thus one group of participants receive the new treatment (intervention group) and another group receive the most common or 'normal' treatment (control group) (Matthews 2000). For ethical reasons the treatment being tested has to be equal to or better than the most common treatment used (*ibid*.). It can be that more than one treatment is tested (*ibid*.), which may mean that more than one intervention group is required. There needs to be an equal chance of a participant been selected to any group to reduce bias and this allows for each group to be comparable in entry characteristics and thus representative of the

study population (Friedman *et al*. 1998). This allocation process is referred to as 'randomisation' (Matthews 2000), the concept of which was introduced by Fisher in the 1920s (Friedman *et al*. 1998). Both treatment and normal procedure are provided alongside each other which is known as a 'concurrent control' and must be followed for a specific length of time to ascertain the effectiveness of the intervention group(s) compared to the control group (*ibid*.). A RCT therefore allows for empirical evidence to be gained by comparing two or more treatments; this evidence is based on the observations and experiences of the participants (Matthews 2000). RCTs conducted properly ensure that there is no selection bias, and is the most efficient way of testing new interventions (Pocock 2000).

However, it has been argued that RCTs are not necessarily the best method used to test new interventions because they are not participant specific (Snowdon *et al*. 1997). Patients often believe that allocation to an intervention or control group is based on their individual needs (Appelbaum *et al*. 1987). Likewise participants can feel 'deprived' of the best treatment when allocated to the control group (Oakley 1997 cited in Snowdon *et al*. 1997:1338). Randomisation therefore has caused concern for patient welfare and questioned the use of it in clinical trials (Chalmers and Chalmers 1994 cited in Snowdon *et al*. 1997:1337). Researchers have investigated ways of improving this part of a RCT, for instance ensuring potential participants understand informed consent, random allocation and the right to withdraw (Wade *et al*. 2009; Edwards *et al*. 1998; Harth and Thong 1995). Solving these issues can ensure that the participants who enrol on to a RCT will be retained as they have a better understanding of what they have consented to and what a RCT involves.

2.1.2 Eligibility issues, recruitment strategies and study design

Several key issues have been considered to ensure a large enough sample enrol on to a RCT and also complete it, for instance eligibility issues, recruitment strategies and design of the study.

- Strict eligibility criteria may result in a low sign up rate; that is restrictive inclusion criteria will affect the number of people who can participate in a study (Collins *et al*. 1984 cited in Chiang *et al*. 2001:208). For instance a study involving pregnant women on a low income to assess a nursing

intervention had three specific eligibility criteria; from 5,230 women screened only 60% were eligible to participate (Moore 1997). Participants can also become ineligible after the trial has commenced, for example moved out of the study area after enrolment (Hellard *et al*. 2001).

- The degree of face-to-face contact with the research team can have negative or positive consequences on how well participants engage with the research. For instance a study comparing postal questionnaires to telephone surveys and face-to-face interviews, found that participants were more likely to answer sensitive questions in a postal questionnaire but there was a low response rate to this type of data collection (Perneger *et al*. 1993). Face-to-face recruitment however can be influential on a person's decision to consent to participate in a RCT compared to someone who is contacted in writing or over the telephone (Wilson and Rose 1998).
- The design of the study can be problematic for example, on examining the response rates to questionnaires in Western Sydney it was found that a shorter questionnaire produced a higher response rate compared to a longer questionnaire (Kalantar and Talley 1999). Even where the study is held can have an impact on recruitment rates for instance, from a parenting skills study it was noted that the programme been offered nearby to participants' homes and at times viewed to be convenient by the participants encouraged sign-up to the trial (Gross *et al*. 2001).

2.1.3 Attrition

Studies have also been conducted on how to reduce attrition (drop outs) from RCTs, as attrition can affect the outcomes of a RCT. Such studies have considered ways of increasing retention by providing incentives to people to 'encourage' participation. This part of a RCT is an important area to study because if attrition can be reduced it will prove beneficial to researchers from all disciplines who engage in the methodology of RCTs.

- Attrition can occur for several reasons, for example in a study assessing what motivates participants with low income from different ethnic groups to participate and to withdraw from a parenting trial, the type of reasons given for withdrawing were: lack of time, changes in job schedule and too much stress (Gross *et al*. 2001).

- A fundamental part of a RCT is to have a large sample size completing the study to ensure enough data to give the statistical analyses sufficient power (Friedman *et al*. 1998). This is required to show statistically whether an intervention is more effective than 'normal' practice. For instance a study assessing the effect of employment support for people with severe mental health had a drop out rate of 29% which was significantly higher in the control group (Burns *et al*. 2007). Therefore, attrition can affect the outcomes of a trial and thus the validity of the results and subsequently whether the intervention is introduced into clinical practice.
- Drop outs and incomplete data have an effect on the interpretation and analysis of the results gathered from a trial (Pocock 2000) which can differentially weight the results if the drop out rates differ between intervention group(s) and the control group (Abramson 1990). This depends on the type of analysis performed. For instance, a pragmatic approach or analysis by intention to treat includes withdrawals, whereas an explanatory approach or analysis of compliers only analyses those who completed the trial and excludes withdrawals and incomplete data (Pocock 2000). Therefore, if an explanatory approach is applied to the data and there are an uneven number of drop outs between intervention group(s) and the control group then this could give a misrepresentation of the results. Similarly incomplete data included in a pragmatic approach could also be misleading. Thus participants who drop out of a trial can have a negative effect on the results such as causing bias to increase and statistical power to decrease, which is why it is important to try and retain participants in a study (Leon *et al*. 2007).
- Yet there is a positive angle to attrition which is attrition could indicate the effectiveness of an intervention i.e., if the number of drop outs are fewer for one specific group compared to another, then it could indicate the effectiveness of that method (Pocock 2000).

2.2 Why do people enrol in a Randomised Control Trial?

Researchers examining the motivations of participants in signing up for (or declining participation in) randomised studies have revealed several key rationales: 'the greater good', 'personal relevance/benefit', 'risk perceptions'.

2.2.1 The greater good

A recent publication assessing three bio-medical studies in the United Kingdom (UK) concluded that participants often engage in RCTs for the 'public good' (Dixon-Woods and Tarrant 2009). This conclusion echoes the findings from a paper regarding recruitment and retention strategies based on a RCT performed in Australia where 'the greater good' was one of the most common reasons given as to why people agreed to participate in a study (Aitken *et al*. 2003). Sammons *et al*. (2007) also noted that 31% of parents allowed their child to take part in the PIVOT study (a UK trial testing treatment types for community acquired pneumonia) in order to 'help other children'. The 'greater good' could also be applied to reasons such as 'contributing to research' as recorded from a study of Sudden Infant Death Syndrome in New Zealand (Hayman *et al*. 2001). Likewise, 27% of parents who consented to their child participating in the PIVOT study did so as they felt the study contributed something to science (Sammons *et al*. 2007). This response was also given in a comparative study of 35 adult withdrawals with 35 adults who completed a study which used participants from a multicentre RCT on asthma treatment (Janson *et al*. 2001).

2.2.2 Personal relevance/benefit

The perception of a trial as having a 'personal relevance/benefit' can also motivate people to take part; 18% of parents who consented to their child taking part in the PIVOT study rationalised doing so because they saw the study to be of a benefit to their own child(ren) (Sammons *et al*. 2007). This finding is echoed by Gross *et al*. (2001) who reported that in a parenting skills study, parents participated to improve their own parenting skills and to discuss their experiences with other parents. In drug and other treatment trials it is a well-known phenomenon that participants enrol in the hope of being randomised to a new type of treatment that may prove beneficial for their condition (Kerr *et al*. 2006).

2.2.3 Risk perception

Risk perception is another factor that has an influence on whether someone agrees to participate in a trial. A study investigating why mothers in Israel chose to allow their newborn infants to participate in medical research found that the proportion of mothers who made the decision to consent decreased as the apparent 'riskiness' of

the study increased; if there were no perceived risks to the infant, parents were more likely to consent, and those who consented to research that appeared risky were perceived to be acting altruistically (Maayan-Metzger *et al*. 2008). Similarly 81.3% of parents approached consented to their child taking part in a clinical anaesthesia or surgery trial (Tait *et al*. 2003); these parents perceived the risk to be low, were more certain of their decision, more trusting of the medical service, had a better understanding of the study, and had a high perception of the importance and benefits of the study.

2.3 Participant loss in Randomised Control Trials

2.3.1 Defining 'a drop out'

Piantodosi (1997:521) defines drop outs as "study subjects who stop taking the treatment to which they were assigned but remain evaluable for follow-up". However Friedman *et al*. (1998:205) provide a more detailed definition of a drop out as "a person assigned to an intervention group who fails to comply with the intervention regimen. If the control group is either on a placebo or on no standard intervention or therapy, the drop-out is equivalent to a cross-over". Pocock (2000) states that drop outs can be categorised into two types of protocol deviation: non-compliance - where the participant does not adhere to the method they were assigned to; and withdrawal - where the participant withdraws or has an incomplete evaluation; protocol deviation can occur for numerous reasons such as in a drug trial the participant may wish to stop due to potential side effects of the drugs (Friedman *et al*. 1998).

The specifications of a drop out have to be relevant to the trial being conducted, i.e., the requirements of the participants for the trial to be statistically viable will determine how a drop out is defined, as the following three examples show. In a study assessing what motivates low income ethnic minority parents to enrol in a parenting trial and why some drop out, the criteria for a drop out was a parent who enrolled in the parent training groups but only attended one or none of the parent groups or did not attend the post-intervention assessment (Gross *et al*. 2001). In a breastfeeding study where participants were expected to make weekly telephone calls for 26 weeks, drop outs were defined as mothers who did not call at all as well

as those that called fewer than four times (Ball 2007). In a study on how to ensure retention in prenatal care, a drop out was defined as a participant who did not complete the required three interviews (Tough *et al*. 2007).

Exclusions, withdrawals and refusals are additional terms that are used to refer to people who stop participating or do not commence participating in a clinical trial.

- Exclusions are where people are screened but do not meet all the eligibility criteria therefore they are not randomised into a group and are not included in the results, but can be useful for providing data about why they were ineligible and whether the eligibility criteria should have been widened (Friedman *et al*. 1998).
- A refusal is someone who simply declines to take part in a study but meets the inclusion criteria.
- Withdrawals are where participants are randomised in to a group but are not included in the data because of various reasons such as ineligibility discovered after the enrolment procedure, or the participant does not adhere to the treatment they are assigned to (Friedman *et al*. 1998). For example, a withdrawal could be a participant who moves out of the district, or has to withdraw for medical reasons (Pocock 2000). However, withdrawal does not necessarily mean that follow-up procedures cannot be conducted; in particular this can be useful in finding out why participants withdraw from RCTs (*ibid*.). If participants are withdrawn for reasons that are not in relation to the trial it could be that they are omitted from the results as 'lost to follow-up' (*ibid*.).

2.3.2 Who is most likely to drop out of a Randomised Control Trial?

Many researchers have highlighted the characteristics of participants who dropped out of their studies. In a RCT on prenatal care in Canada 11% (*n*=197) of the sample dropped out and seven percent (*n*=124) of the sample were unreachable; these women tended to be of a younger maternal age, had a lower education level, were on a low income compared to women who remained in the trial; non-Caucasian women were more likely to drop out whilst those without partners were more likely to be unreachable (Tough *et al*. 2007). A similar conclusion was reached from a study of a parenting education programme aimed at preventing child

maltreatment in Seattle, Washington with a high drop out rate of 28% (*n*=48) who tended to be women who were teenagers, African-American, had a low Home Observation for Measurement of the Environment (HOME) score and attended a particular clinical site (Danoff *et al*. 1994). However other factors such as marital status, educational attainment, rates of referral to Child Protective Services or low Nursing Child Assessment Teaching Scale (NCATS) score, did not differ between drop outs and those who completed the study (*ibid*.). Researchers who conducted an asthma treatment study in America noted that females from ethnic minority groups were more likely to drop out, and the reasons given were that the study requirements were inconvenient due to work commitments and was time consuming (Janson *et al*. 2001).

El-Khorazaty *et al*. (2007) also highlight that within the literature on recruitment and retention it appears that women from US minority ethnic groups (in particular, African-American and Latinas) of low income are less likely to engage in a study and if they do they are less likely to complete it. They assessed recruitment and retention strategies in a RCT – Project DC-HOPE -- a behavioural and counselling study aimed at reducing smoking, secondary smoking, depression and intimate partner violence amongst pregnant low-income minority women, in particular African-American and Latina women in Washington DC, with the aim to also reduce pregnancy outcomes associated with smoking. There were 1070 women who enrolled on the trial, 1044 of which were African-American women; 849 women (79% of those enrolled) completed the trial. The high recruitment and retention figures were attributed to the design of the study which was targeted at this sample of the population. Such strategies implemented were:

- Study design (e.g., study activities occurred at prenatal appointments to reduce inconvenience).
- Contact (participants received regular telephone contact with the research team).
- Financial incentives (these were given at specified times of participation).
- Research team (they were mainly African-American females who were trained to be responsive to the participants by being someone the participant felt comfortable confiding in).

- Clinical staff co-operation (the study was explained to the staff and staff received a partial salary for undertaking the duties of collaborator between research staff and pregnancy advisors).

As mentioned, women of a younger maternal age have been cited as more likely to drop out of a clinical trial (e.g., Tough *et al*. 2007; Danoff *et al*. 1994). This is reiterated by the argument that older adults are more committed to participating in a project and are therefore less likely to drop out (Areán and Gallagher-Thompson 1996). In a bed-sharing and breastfeeding study conducted in the North-East of England, it was highlighted that even though the cohorts in the study were older than the average maternal age (because one of the eligibility criterion was that the mother had to have the intention to breastfeed) it was still the youngest women who tended to drop out of the study; this was coupled with mothers who were on a lower but not necessarily low income (Ball 2007).

It is argued that attrition is higher amongst participants allocated to the control group (Kerr *et al*. 2006). Yet, in a longitudinal RCT which compared patient self-management of oral coagulation with patient self-testing with participation lasting for six months, the drop out rate was 22% (*n*=24) and was not significantly different between the control and intervention groups (Gardiner *et al*. 2005). A significant difference of drop out rates between participants in a control group and an intervention group was highlighted however in a study assessing the effect of providing supported employment to people with severe mental health problems, with a higher drop out rate in the control group (Burns *et al*. 2007).

2.4 Anthropological perspectives on trial participation and retention

Various theories employed by anthropologists might be useful in thinking about how to encourage participation and retention in RCTs. These theories can be derived from a biological and/or social anthropological perspective.

2.4.1 Biological anthropological approach

An evolutionary approach can be applied to help understand why people participate in RCTs by considering the evolution of co-operation, in particular reciprocal

altruism (Trivers 1971), the Prisoner's Dilemma game theory (Axelrod and Hamilton 1981; Hargreaves Heap and Varoufakis 2004) and the Tit-For-Tat strategy (Axelrod and Hamilton 1981); understanding why people withdraw from a trial can be explored from the perspective of the Free Rider strategy (Hargreaves Heap and Varoufakis 2004). Each of these theories suggests that peoples' actions in certain social situations are the current manifestations of evolved behavioural strategies for negotiating interpersonal relationships.

2.4.1.1 Reciprocal altruism

Reciprocal altruism is viewed as part of the evolution of social organisation; reciprocal altruism involves altruistic acts between a pair of individuals that occur over time, with both taking the role of the giver and the receiver (Stevens and Hauser 2004). Altruistic acts are not exclusive to humans; grooming amongst non-human primates is believed to be an altruistic act that creates and reinforces social bonds (Carpenter 1942 cited in Cheney and Seyfarth 1990:37); also regurgitating food for another bat amongst vampire bats is an act that is reciprocated (Wilkinson 1984 cited in Cardwell *et al*. 1999:502). It is not necessary for reciprocal behaviour to be like-for-like, i.e., grooming can be returned by coalition; however general principles are that the benefits generally outweigh the costs and the strategy is advantageous to all concerned (Boyd and Silk 2003). Trivers (1971) cites three requirements for reciprocal altruism: interaction between the pair must happen often so that the altruistic act can be reciprocated; the pair need to be able to register support given and received from particular partners; and the individual must provide support to the one who gives support. For altruistic acts to be beneficial then the more acts there are between a pair, the better the return, however, if an individual does not know the other person, then one member of the dyad must make the first move with uncertainty of whether the act will be reciprocated (Roberts and Sherratt 1998). In applying this principle to medical research Pruitt and Kimmel (1977 cited in Dixon-Woods and Tarrant 2009:2216) suggest that participants expect their co-operation to be met with co-operation by the researchers in the form of considering participants' well-being; thus co-operation is a two way interaction. In the context of a RCT reciprocal altruism theory would therefore suggest that prospective participants may be more likely to 'co-operate' with a trial invitation if they are a) approached by an individual they trust and with whom they are likely to establish an

ongoing relationship, and b) receive assurance that they will accrue some form of benefit from their co-operation.

2.4.1.2 Game theory

The uncertainty regarding another person's actions with whom one might co-operate is often conceptualised using 'game theory', the most basic variant of which is the Prisoner's Dilemma (Axelrod and Hamilton 1981; Hargreaves Heap and Varoufakis 2004). The Prisoner's Dilemma addresses the options open to an individual in a situation where a decision has to be made to either co-operate (for mutual gain) or defect (exploit the co-operation of the potential partner for individual gain) and requires an element of trust or distrust of the opponent (*ibid*.). In this situation what might be gained (the pay-off) depends on the choices made by both players. The outcomes are: both players co-operate, both defect, one co-operates and the other defects; each yields different outcomes for each player (Axelrod and Hamilton 1981; Cardwell *et al*. 1999). Stevens and Hauser (2004) suggest that in the Prisoner's Dilemma if one defects then the reward is immediate and direct but the opponent is exploited, if one chooses to co-operate then the reward is cumulative and long term. Decisions are therefore made depending on whether the players want future rewards or instant ones.

The Tit-For-Tat (TFT) strategy is a decision rule for how one behaves in the face of the Prisoner's Dilemma (Axelrod and Hamilton 1981). TFT specifies that a player's first 'move' must be co-operative and the subsequent moves copy the opponent's previous move (Axelrod and Hamilton 1981; Hargreaves Heap and Varoufakis 2004). Therefore, if the opponent defects then they will be punished in the next interaction and if they co-operate this will be met with co-operation (*ibid*.). Thus this is a way of keeping defection to a minimum (Cardwell *et al*. 1999). The TFT model is not just apparent in humans as Milinski's (1987) simulated experiment with sticklebacks showed (sticklebacks copied their opponent's previous action). In the context of a clinical trial where a researcher is soliciting the co-operation of a potential participant a TFT strategy would suggest that researchers could offer potential participants a positive benefit for their co-operation from the outset, and reward compliance with further reinforcement of those benefits, as a means of recruitment and retention.

When there is an altruistic concern above and beyond a simple exchange of co-operation it changes the game from a Prisoner's Dilemma to one of moral motivation (Hargreaves Heap and Varoufakis 2004), a situation that is arguably more relevant to clinical settings. For example, Titmuss (1970 cited in Hargreaves Heap and Varoufakis 2004:188) noted that countries like the United Kingdom had higher rates of blood donations where donors receive no financial advantage compared to countries like America where people are paid for blood donations, thus in this example moral motivation outweighed financial gain. Creating a sense of moral motivation may therefore help with retention in RCTs, particularly for participants who stand to receive no direct benefit from their involvement, thus an example of people participating in RCTs for the 'greater good'.

If a game theory player repeatedly defects this could be considered an example of a 'Free Rider' strategy. A Free Rider occurs when the player benefits from the actions of others without having to make any contribution and thus receives high benefits at no cost (Hargreaves Heap and Varoufakis 2004). For instance, in the provision of public goods a Free Rider does not contribute to the public good whilst others do, but the Free Rider also benefits (*ibid*.). In an experiment on providing prepaid incentives to increase response rates to telephone surveys, Free Rider behaviour was present as 22.3% of the participants did not respond to the surveys after receiving a prepaid incentive (Singer *et al*. 2000). To overcome the Free Rider problem it is necessary for there to be punishment of/or sanctions against defectors, and for reciprocity to occur.

2.4.2 Social anthropological approach

From a social anthropological perspective, participation in and withdrawal from a RCT may be likened to observance of the rules of gift exchange, in particular reciprocity (Sahlins 1972) and/or of building social obligations within a social network (Mauss [1925] 1967).

2.4.2.1 Reciprocity

Gift exchange is a form of social interaction governed by a set of rules which Mauss listed as being a set of obligations (Hendry 1999). There are three forms of exchange: reciprocity, redistribution and market principle (Polanyi [1944] 1957

cited in Eriksen 2001:184). Reciprocity occurs where products of some sort pass back and forth according to a specified relationship; redistribution refers to where a product is given to one person who then redistributes it; market economy refers to how products are sold for money (in a Western society) and then the money is used to purchase other products with the aim of gaining more products, money or both (Peoples and Bailey 2006).

Sahlins (1972) argued that reciprocity is either; generalised, balanced or negative. Generalised reciprocity is a weak obligation to reciprocate and usually takes place amongst family members; there is no specific time set for return. This implies a type of relationship for exchange such as the love a mother gives to a child or a birthday present. Balanced reciprocity usually occurs as a direct exchange; gifts are given at the same time or within a short period of time, and are of equal value. This is more likely in a formal relationship such as where money is exchanged for goods of the same value. Negative reciprocity is where there is an attempt to gain something at the expense of others; relationships are harmed by this exchange as it is impersonal and for self-gain, normally between strangers. For example, theft of property or bartering can come under this category. Generalised reciprocity could be applied to participants who complete RCTs with reciprocation in the form of a financial incentive upon trial completion given for participant co-operation.

2.4.2.2 Building social obligations

Marcel Mauss ([1925] 1967) proposed that gift giving is made up of a set of obligations, that is; the obligation to give, accept and reciprocate. It is a form of social interaction where exchange is a medium for communication which needs to be reciprocated but does not have to be like-for-like, i.e., sending a letter may be reciprocated with a visit from the receiver to the sender (Hendry 1999). Mauss ([1925] 1967) said that the obligation to give is no less important as to receive in some societies, therefore when given a gift there is the obligation of the receiver to accept and then return. In the context of a clinical trial the social obligation of reciprocity might be used to foster participant compliance and retention. The receipt of a gratuity at the onset of a trial might foster a sense of social obligation in a participant that might prove more compelling than a promise of a gratuity upon completion. The development of a sense of community and relationship between

researchers and participants may also help to cement a sense of reciprocal social exchange such that participants will remain engaged until the conclusion of the study.

Anthropological theory might therefore be informative when designing RCTs in that researchers can implement suitable recruitment and retention strategies based on the underlying biological and social reasoning behind our decision making. Anthropological theory can provide an understanding as to why people volunteer to participate in RCTs and what motivates some people to complete a RCT and others to withdraw.

2.5 Practical interventions implemented to reduce attrition

Research has been conducted on types of interventions that may assist in reducing attrition in clinical trials, in particular relationship based interventions, incentive based interventions, combination of interventions, and timing of providing an incentive. Each of these interventions has specific properties to which anthropological theory can be applied.

2.5.1 Relationship based interventions

A number of studies have revealed that regular contact with the researcher by telephone or in person reduces attrition as it helps to create a more personal relationship between participants and researchers (Motzer *et al*. 1997; Moore 1997; Gross *et al*. 2001; Hellard *et al*. 2001; Aitken *et al*. 2003; El-Khorazaty *et al*. 2007) therefore fostering the social obligation mentioned above. For instance, around 90% of participants in a study on the progression of myopia in children stated that the staff and their manner towards the participants (i.e., staff being friendly, encouraging and responsive) was why people continued to participate, along with the standard of care they received (Dias *et al*. 2005). A systematic review of screening programmes also listed continual contact as being beneficial to reducing attrition, with rewards and incentives being less effective (Jepson *et al*. 2000). In the Water Quality Study, a longitudinal study in Australia, there was a high number of participants (97.7%) who stated that regular contact with the research team in the form of monthly newsletters, which kept participants well informed, was one of the

strongest reasons for continued participation thus reducing attrition (Hellard *et al*. 2001).

Personal contact need not necessarily be verbal or face-to-face, but thank you letters and certificates of appreciation can also provide a personal touch and a sense of achievement (Motzer *et al*. 1997). Giving the participant extra time to complete surveys if they have low literacy skills also demonstrates social sensitivity and builds positive relationships (Cooley *et al*. 2003), as does providing extra information to participants who need clarification of what is required of them (Motzer *et al*. 1997). Another factor associated with building relationships is including logos on all correspondence (Motzer *et al*. 1997; Aitken *et al*. 2003) as symbols are often used to create a sense of identity and belonging by providing a set of people with something they can identify meaning to (Hendry 1999).

2.5.2 Incentive based interventions

Other studies have highlighted the effectiveness of providing participants with incentives to aid retention in trials such as, cash incentives (e.g., Motzer *et al*. 1997; Moore 1997; Cooley *et al*. 2003), lottery scratch cards, prize draws (Hellard *et al*. 2001), free child care and meals when attending study groups, and reimbursement for travel expenditure (Gross *et al*. 2001).

One study in America, which assessed different incentives, was aimed at increasing response rates to a self-administered survey on smoking amongst teenagers who were enrolled in a managed care organisation (MCO) project (Martinson *et al*. 2000). This study randomly allocated participants into one of four incentive groups: no incentive (control group), $2 cash incentive, $15 cash incentive and $200 prize draw incentive. The researchers found that the $15 cash incentive group had a higher response rate compared to the other intervention groups, which suggests that participants in this study responded better to an amount that was substantial and guaranteed compared to a smaller guaranteed amount or a larger non-guaranteed amount. Similarly, a study performed in the UK (North and West Birmingham) where the incentive to complete a postal questionnaire was a £100 gift voucher draw, it was noted that the incentive had no significant effect on the response rate (Roberts *et al*. 2004). However in a paper examining response rates to

questionnaires, receiving an instant lottery ticket was recorded as being more appealing to participants than not receiving anything even though there was no guarantee of a financial gain (Kalantar and Talley 1999).

Cash incentives were tested on postal surveys (regarding working with alcohol misusing patients) sent to a sample of General Practitioners (GPs) in England and Wales who had not responded to two previous surveys. The study highlighted that when offered a cash incentive the response rate increased compared to no incentive, and the cash incentive yielded a better result than an offer of donating money to charity; also the response rate was lowest for older GPs and that male GPs were more inclined to reply when offered a cash incentive (Deehan *et al*. 1997). Raising the incentive proved to increase the response rate in a follow-up questionnaire survey in America amongst radiologic technologists (Doody *et al*. 2003). Thus it could be argued that in situations where a financial incentive is offered, participants are displaying Prisoner's Dilemma behaviour - that is, reciprocation is given in response to the promise of a reward, this could also be an example of reciprocal altruism and of generalised reciprocity (i.e., participation is not rewarded immediately and is not necessarily like-for-like).

It is not just monetary incentives that encourage people to participate in trials but other gifts or reimbursement for expenditure can too, for example, in a parenting skills study receiving a video tape of their child was seen as more rewarding by participants than receiving a monetary incentive (Gross *et al*. 2001).

2.5.3 Combination of interventions

If relationship based and incentive based interventions can reduce attrition then it is possible that combining both types of interventions together could reduce attrition further, which was found in a health survey study in Geneva amongst young adults aged 20 years and under (Perneger *et al*. 1993). Perneger *et al*. (1993) looked at monetary incentives, postcard reminders, and a combination of both, and showed that after two weeks, the intervention which used a combination of both methods yielded the highest response rate; when this method was applied to all participants for the remainder of the study period, retention increased, so that the response rate between each intervention group was almost the same. Thus this combination of

incentives increased retention in the groups that had previously received either monetary incentives or postcard reminders. Similarly a meta-analysis on study techniques of mail survey responses concluded that giving follow-up notification, providing postage, sending out return envelopes and giving monetary incentives all increased response rates (Yammarino *et al*. 1991).

2.5.4 Timing of interventions

Singer *et al*. (2000) studied the effectiveness of promised and prepaid incentives on increasing the response rate to answering a telephone survey (The Survey of Consumer Attitudes, which occurred over two years), and found that a prepaid incentive was more successful in increasing the response rate to the survey compared to a promised incentive. This result echoes a meta-analysis of 38 studies, which aimed to evaluate different types of rewards, and showed prepaid incentives, whether monetary or not, were more effective than promised incentives; however prepaid monetary incentives yielded the highest response rate of all (Church 1993).

2.6 Application of anthropological theories

2.6.1 Biological perspective

In the context of clinical trial participation reciprocal altruism and the game theory approach could be applied to understanding what motivates people to participate in a clinical trial and also provide an explanation as to why people withdraw or refuse to participate. Thus for example from an evolutionary perspective, where a participant receives regular incentives or a prepaid incentive this could be likened to the TFT model in that the participant responds to the incentive by co-operating in order to continue to receive future benefits. For instance receiving newsletters or a gift could be met with the participant fulfilling their role in the trial. The Prisoner's Dilemma is more long term in that to co-operate reaps a reward at the end of the trial and relies on a great deal of trust on behalf of the participant, for example the normal protocol of the NECOT trial is for participants to receive a £10 thank you gift at the end of their trial participation. Similarly, reciprocal altruism would explain why people participate for no immediate reward or benefit too. Thus the altruistic act of participation by people in the NECOT trial is returned in the form of

a thank you gift. A participant who receives a prepaid incentive and then does not engage in the trial could be said to be a Free Rider.

2.6.2 Social perspective

From a social anthropological perspective, the offering of incentives and/or rewards for participation in trials can be likened to Sahlins' principles of gift exchange and Mauss' set of social obligations. That is, the interaction between researcher and participant involves following the rules of both gift exchange and building social obligations. For instance, where prepaid incentives, regular correspondence with the research team or free gifts have been given the participant has the obligation to accept and then reciprocate. Reciprocation does not have to be like-for-like; for example reciprocation to a prepaid incentive could be in the form of making weekly telephone calls (a requirement of the NECOT trial) thus an example of generalised reciprocity and of social obligations. A participant who receives a gift but does not engage in the study can be explained as showing behaviour associated with negative reciprocity and also not adhering to the obligation to reciprocate.

2.7 Hypotheses

The RRCT project looked at interventions designed to reduce attrition from the ongoing North-East Cot (NECOT) trial that are derived from anthropological perspectives and assessed their effectiveness. These interventions are: incentive based, relationship based, prepaid incentives, or a combination of interventions, and tested the impact of an enhancement on the normal procedures adopted by the NECOT trial. The following hypotheses were tested:

Hypothesis 1: It is expected that there will be a higher attrition rate in the RRCT project control groups compared to the RRCT project intervention groups (social obligation, TFT game theory and reciprocal exchange).

Hypothesis 2: Participants who receive regular contact with the research team will be less likely to drop out of the NECOT trial (social obligation).

Hypothesis 3: The participants who receive both regular contact and a prepaid incentive will have the lowest attrition rate (social obligation plus TFT game theory).

Hypothesis 4: Participants who receive their thank you gift when they have given birth (prepaid incentive) will have lower attrition compared to the RRCT project control groups (TFT game theory).

Hypothesis 5: Receiving free samples before giving birth and being entered into free prize draws after giving birth, will have an affect on reducing attrition compared to those participants in the RRCT project control groups (reciprocal exchange).

Chapter 3: Methodology

3.1 Relevance of the RRCT project to the NECOT trial

The North-East Cot (NECOT) trial (a longitudinal RCT) aims to assess the effectiveness of side-car cribs (intervention) on postnatal infant feeding and sleeping practices (in the first six months after birth in the North-East of England). It is necessary to have a large sample size completing the NECOT trial to ensure enough data are gathered to give the statistical analyses sufficient power. As participants are enrolled onto the NECOT trial at their 20 week routine antenatal scan, then expected to make follow-up telephone calls for 26 weeks after delivery, participants are engaged in the NECOT trial for between 43 and 48 weeks (allowing for the accuracy of their expected date of delivery [EDD]). This is a substantial length of time to be involved in a study and it is paramount to keep participants interested in the study to ensure a high completion rate and low attrition. The RRCT project was designed to test various intervention ideas that have been trialled in other studies in an attempt to ensure a high retention rate in the NECOT trial by providing the following to NECOT participants: a) regular contact, b) regular incentives, c) a combination of interventions and d) a prepaid incentive.

3.1.1 Normal procedures adopted by the NECOT trial

All participants in the RRCT project followed the normal protocol adopted by the NECOT trial, which are detailed as follows:

- A female researcher approached potential participants at their 12 week scan and provided them with a participant information leaflet.
- The expectant mothers were approached again by a female researcher at their 20 week routine scan and asked if they wished to participate in the NECOT trial. If they did, they were given an enrolment form and a consent form to complete, and the procedure that followed was explained to the new recruits at this stage.
- Once the new recruits' data were entered onto the NECOT database, the participants were sent a welcome letter.

- When participants reached 32-34 weeks gestation, providing they were still eligible to take part, they were sent a letter and a sticker, for their hand-held hospital notes, stating which cot they had been randomised to.
- When participants returned home after giving birth and providing they were still eligible, weekly postcards were sent out to remind them to ring the free-phone number that prompted them to enter their follow-up data; they were also sent a questionnaire to establish whether and when they received the cot-type they had been allocated and whether anything prohibited them from breastfeeding.
- At the end of the 26 week follow-up period the participants were sent a thank you letter, a completion questionnaire and a £10 high street gift voucher as a thank you gift.
- Throughout the trial if the participant had a query a member of the team would ring to answer the query. If the participant missed three consecutive calls to the telephone data system they were contacted to ascertain if there were any problems with making the telephone calls or if they wished to withdraw from the study.
- The telephone system allowed for participants to leave their telephone number if they wished a member of the NECOT team to ring them.
- Other arrangements were made for participants who were unable to make telephone calls, for example, they did not have a touch-tone telephone or they only had a mobile telephone; such arrangements were: ringing participants to collect their data over the telephone, providing participants with a FREEPOST envelope for them to return their postcard in with their answers marked, or email their answers to a member of the research team.
- Any paperwork (which all included the NECOT logo) that was sent to the participants, to be returned to the NECOT team on completion, was accompanied by a FREEPOST return envelope to ensure that the participants did not incur any unnecessary expenditure.

3.2 Interventions

Several interventions were applied to consecutive and mutually exclusive groups of participants to ascertain what would be most effective in preventing attrition in this

trial. The interventions were selected based upon the theoretical considerations of game theory, reciprocal altruism, reciprocity, moral and social obligation as discussed in Chapter 2. All of the methods chosen had been previously applied in other trials; the RRCT project therefore aimed to test their validity in the context of the NECOT trial and to ascertain which (if any) aspects of anthropological theory might be useful in reducing trial attrition.

3.2.1 Relationship based intervention (intervention group 1)

A relationship based intervention was developed based on findings from other research (e.g., Motzer *et al*. 1997). The relationship based intervention comprised sending the participants regular newsletters (see appendix A), a congratulations card (see appendix B) and a calendar (see appendix C) in order to build a social relationship between researcher and participant; the congratulations card and calendar were both printed on card. The NECOT logo was displayed on these items as the use of logos were also found to help increase retention rates (Motzer *et al*. 1997; Aitken *et al*. 2003). The idea behind sending out these items was to create a relationship between researcher and participant by keeping regular contact with the participant and to bridge gaps in contact throughout the stages of the NECOT trial. The newsletters were sent to the participants when they were 27 weeks pregnant, 34 weeks pregnant, when their baby was seven weeks old, 14 weeks old and 21 weeks old (see Table 3.1). When the participant gave birth they were also sent a congratulations card and a calendar (which had the dates that the participant was supposed to ring the free-phone number circled).

Intervention group 1 received five newsletters in total, each of which provided information about a member of the research team, a topic regarding the trial process at relevant points in the participants' participation and a questions and answers section which related to the topic covered in the newsletter. The newsletters were sent at specific times to coincide with certain stages in the NECOT trial as detailed in Table 3.1.

Table 3.1: Delivery of relationship based intervention

	When sent	NECOT stage	Topic covered
Newsletter 1	27 weeks gestation	Following enrolment	What is the point of a RCT?
Newsletter 2	34 weeks gestation	Following notification of randomised allocation	The importance of control groups
Newsletter 3	Baby 7 weeks old	Follow-up procedure	Necessity of the follow-up procedure
Newsletter 4	Baby 14 weeks old	Follow-up procedure	Change in feeding methods
Newsletter 5	Baby 21 weeks old	Follow-up procedure	Note of thanks and trial completion

Information selected for inclusion in the newsletters was chosen on the basis of trying to provide a sense of belonging to the trial, getting to know the research team, and to reassure, reiterate and reconfirm the key features of participating in a RCT. The topics covered in the newsletters were tackled in an attempt to reduce attrition in the NECOT trial.

- Reiteration of RCTs – often participants do not fully understand the implications of a RCT and in particular the process of randomisation (Snowdon *et al*. 1997; Wade *et al*. 2009; Edwards *et al*. 1998; Harth and Thong 1995). Providing extra information on this point could give clarity to the subject and may stop participants withdrawing.
- Importance of a control group – attrition can often be greater in control groups (Kerr *et al*. 2006; Burns *et al*. 2007). Therefore highlighting the importance of a control group on the successful execution of a RCT could reduce attrition amongst people allocated to a control group.
- Necessity of follow-up procedures – again there is often a lack of understanding of the full process of a RCT including follow-up procedures (Snowdon *et al*. 1997). Providing this information may retain people in the trial.
- Feeding methods – it is still necessary for participants to continue with the follow-up procedure even if they cease breastfeeding, therefore a misunderstanding of trial participation could result in withdrawals when participants stop breastfeeding. This information was supplied at a time near

to when participants' babies reached four months of age as this is reported as being when breastfeeding prevalence tails off (Bolling *et al*. 2007).

- Note of thanks – gratitude for participation gives a sense of achievement (Motzer *et al*. 1997).
- The importance of completing the trial – again providing this information reiterates the trial process (Snowdon *et al*. 1997).

3.2.2 Incentive based intervention (intervention group 4)

The incentive based intervention included sending participants free gifts as providing non-cash incentives can have a positive effect on retention (Gross *et al*. 2001); and entering participants into free prize draws as prize draws can be used as an incentive (Hellard *et al*. 2001). Each participant received a prize in the prize draws as there was one first prize and 74 runners-up prizes. Participants were notified in writing (see appendix D for an example of the invitation letter), five weeks before each prize draw, that they were being entered into a free prize draw and given the opportunity to withdraw providing they informed the researcher in writing by a specified date. The free samples and prizes were provided at the same intervals as when the newsletters were sent, as detailed in Table 3.2.

Table 3.2: Delivery of incentive intervention

	When sent	NECOT stage	Item sent
Free gift 1	27 weeks gestation	Following enrolment	Breast pads[1]
Free gift 2	34 weeks gestation	Following notification of randomised allocation	Nipple cream[1]
Prize draw 1	Baby 7 weeks old	Follow-up procedure	First prize – baby monitor[2] Runners-up prizes – boxes of breast pads[2]
Prize draw 2	Baby 14 weeks old	Follow-up procedure	First prize - £50 gift voucher[3] Runners-up prizes – 'icy bite' teether rings[2]
Prize draw 3	Baby 21 weeks old	Follow-up procedure	First prize – weaning kit[2] Runners-up prizes – boxes of feeding spoons[2]

[1] Donated by *Lansinoh*
[2] Donated by *Tommee Tippee*
[3] Donated by *Mark's and Spencer*

3.2.3 Prepaid incentive (intervention group 3)

Investigating the effectiveness of prepaid and promised incentives was explored in light of the findings from Singer *et al*. (2000) and Church (1993). This was tested by altering the timing of sending a group of participants their thank you gift for taking part in the NECOT trial. Normal procedure for the NECOT trial was for the participants to receive their thank you gift of a £10 high street gift voucher once they had completed the follow-up portion of the trial (when their baby was 26 weeks old). This was therefore a promised incentive. To test the idea that provision of the thank you gift prior to follow-up might serve to encourage a sense of moral obligation in participants, which hopefully would promote a TFT strategy of subsequent co-operation, this intervention group received their thank you gift when they gave birth before commencing the 26 week follow-up period. This was therefore a prepaid incentive. To avoid any confusion, participants who received a thank you gift voucher as a prepaid incentive were informed that they would not receive another voucher on completion of the trial (see appendix E for a copy of the notification letter).

3.2.4 Combination of incentives (intervention group 2)

Yammarino *et al*.'s (1991) and Perneger *et al*.'s (1993) studies looked at combining interventions, therefore a combination of prepaid and relationship based interventions was investigated in this study, that is, one group of participants received the newsletters, congratulations card and calendar (relationship based) and their £10 thank you gift voucher when they gave birth (prepaid).

To summarise, two control groups received the normal procedures adopted by the NECOT trial only and the intervention groups received an enhancement to this as follows: intervention group 1 received regular newsletters, congratulations card and a calendar (testing hypothesis 2); intervention group 2 received regular newsletters, congratulations card, a calendar and the participants were sent their £10 thank you gift voucher when they gave birth as a prepaid incentive (testing hypothesis 3); intervention group 3 received their £10 thank you gift voucher when they gave birth as a prepaid incentive (testing hypothesis 4); intervention group 4 received free

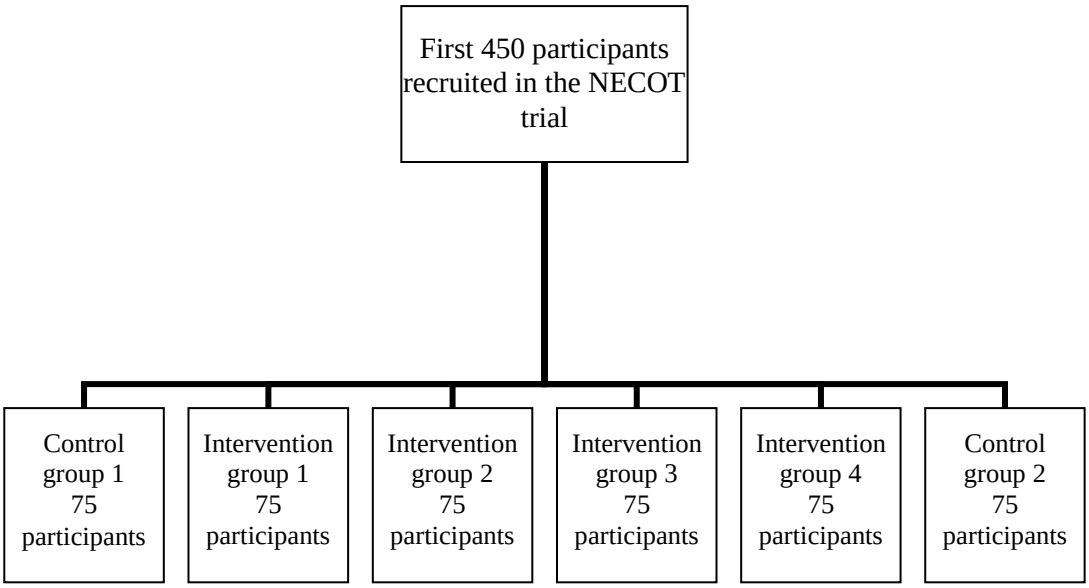
samples and were entered into three free prize draws (testing hypothesis 5). Control group 1 and control group 2 followed the standard NECOT protocol only.

3.3 Allocation

Allocation to the six test groups (two control and four intervention groups) was performed consecutively in blocks in order to efficiently implement and deliver the interventions. For example in order to perform free prize draws then the expected date of delivery (EDD) of all the participants receiving this incentive needed to be within a few days of each other so that their babies reached seven weeks, 14 weeks and 21 weeks of age around the same time, thus it was not possible to have a participant who delivered in March 2008 in a prize draw group with a participant who delivered in November 2008. Therefore participants were selected into a control group or an intervention group by alternation (Torgerson and Torgerson 2008). Alternation normally consists of participants been allocated to a group alternatively i.e., first participant to the control group, second participant to an intervention group, third participant to the control group and so on (*ibid*.). However the allocation in the RRCT project was in blocks based on when the participants were recruited, which coincided with the participants' EDD. It could be argued then that the participants were allocated using trickle or sequential allocation or as participants were likely to give birth around the same time within each group due to the time they were recruited, this could be an example of quasi-alternation, that is been allocated by a common factor such as people born in the same month are allocated to one group (*ibid*.).

To summarise, the first 450 participants recruited in the NECOT trial were allocated to a control group or an intervention group in the RRCT project by their scheduled delivery date as detailed in Figure 3.1.

Figure 3.1: Allocation of participants



It was decided to have two control groups to account for timing of recruitment as this was the first time that the researchers had performed any type of large scale recruitment; having a second control group from those recruited later in the NECOT trial would act as a comparison to ensure that there was no bias in control group 1 due to being recruited first.

3.4 Ethical issues

As per the Association of Social Anthropologists of the Commonwealth's (2005) ethical guidelines ethics, confidentiality, anonymity and informed consent were addressed. The NECOT trial was granted NHS ethical approval by County Durham and Tees Valley 2 Research Ethics Committee (CDTV2 REC). The RRCT project did not alter the original protocol for what was required of participants in the NECOT trial and did not require the recording of any additional data about the participants. The RRCT project was conducted by a member of the NECOT research team whose involvement in managing and analysing data obtained as part of the larger trial had been approved by the CDTV2 REC. As a postgraduate research project ethical approval for the RRCT project was sought and granted by the Anthropology Department Research Ethics and Data Protection Committee, Durham University. Throughout the course of the RRCT project all NECOT participants were identified by an identification number; all data held on computer was securely stored by applying passwords to all documents; any hard copies kept

were locked away securely. NECOT participants remained blind to the RRCT project and all incentives and newsletters received were presented as normal procedures of the NECOT trial.

3.5 Study location

The location of the NECOT study and therefore the RRCT project was The Royal Victoria Infirmary (RVI) hospital, Newcastle-upon-Tyne in the North-East of England. Each year there are around 5,700 babies delivered at the RVI hospital (The Newcastle upon Tyne Hospitals NHS Foundation Trust 2009). The RVI's maternity department is one of the largest in the United Kingdom; it hosts two postnatal wards and a special care baby unit.

3.6 Terminology

For the purpose of the RRCT project the following definitions apply:

3.6.1 Drop outs

The definition of a drop out was based on the definitions previously referred to by Piantodosi (1997) and Friedman *et al*. (1998) and the definition of a withdrawal was based on the definitions provided by Pocock (2000) and Friedman *et al*. (1998). Thus for the RRCT project:

- A drop out was classed as someone who was randomised into a cot type and did not engage in or did not complete the follow-up telephone call procedure as per the specifications of the NECOT trial.
- For the RRCT project, a drop out was categorised into three groups; withdrawals, non-compliers and ineligible.
    - Participants who did not engage ('did not engage' herein) or ceased to engage ('stopped ringing' herein) in the follow-up procedure were classified as non-compliers.
    - A participant who decided to drop out from the trial for their own personal reasons, for example, did not get a side-car cot, or family circumstances made it difficult for her to participate, were classed as a withdrawal.
    - A participant was identified as being ineligible if their eligibility criteria changed rendering them ineligible to participate in the

NECOT trial, i.e., participant gave birth before 37 weeks gestation, baby was transferred to the special care baby unit (SCBU), baby was delivered elsewhere to the RVI, mother had a homebirth and mother and baby did not attend hospital, mother experienced a miscarriage or an intrauterine death, mother moved out of the area prior to giving birth, mother unable to breastfeed due to medical reasons, or baby did not accompany mother home.

3.6.2 Ethnicity

On the NECOT enrolment forms participants were asked to state their ethnicity creating numerous variations, which meant it was necessary to categorise ethnicity into a standard format. Therefore the ethnic categorisation system used by the government for the census records was applied to the RRCT project participants as the 2001 census records were consulted to provide the demographic data of Newcastle-upon-Tyne for the RRCT project (Ward Fact Card 2001). The categories are:

- White (British, Irish, Other White).
- Mixed (White and Black Caribbean, White and Black African, White and Asian, Other Mixed).
- Asian or Asian British (Indian, Pakistani, Bangladeshi, Other Asian).
- Black or Black British (Caribbean, African, Other Black).
- Chinese or other ethnic groups (Chinese, Other ethnic group).
- Not specified/unknown.

3.7 Analyses

Aggregate data were coded and entered into a database using the Statistical Package for the Social Sciences (SPSS) v 14.0. Analyses by Pearson Chi-squared tests (χ^2) were performed to establish the independence between two categorical variables (Stewart 2002; Watt 1993; Madrigal 1999) using 2x2 contingency tables (Hinton *et al*. 2004). The probability of independence has to be <0.05 to show a significant relationship between the two variables (*ibid*.). If the expected frequency in any of the four cells was less than five, the sample was not large enough to assume the pattern shown would be continuous, in these cases Fisher's exact tests were employed (*ibid*.). Fisher's exact tests calculate the actual probability for a 2x2

cross-tabulation table with expected frequency of <0.05 by calculating the frequency distribution in all possible ways (*ibid*.). Independent sample t-tests were consulted to assess the association between continuous and categorical variables (Stewart 2002; Hinton *et al*. 2004; Madrigal 1999). Exploratory data are reported using graphs, tables, figures and percentages.

Chapter 4: Results

The first 450 participants to enrol in the NECOT trial were assigned to six consecutive groups of 75 participants each. The following section explores the socio-demographic characteristics of the sample as a whole and by group in order to ascertain whether they differ in any systematic way.

4.1 Socio-demographic data of RRCT participants

4.1.1 Age

The mean age of the participants in the RRCT project was calculated based on the age of the mother at the point of giving birth, unless the participant withdrew from the NECOT trial before giving birth in which case age was calculated for the mother by her estimated delivery date. Table 4.1 details the mean age of the total sample and of the participants in each allocation group.

Table 4.1: Participant age

	Mean age	Standard deviation (SD)
Total sample	30.9	5.74
Control group 1	31.3	5.78
Intervention group 1	31.3	5.59
Intervention group 2	30.9	5.55
Intervention group 3	31.1	5.87
Intervention group 4	30.0	5.69
Control group 2	30.9	6.06

4.1.2 Marital status

Marital status was categorised as: married/living with a partner (*n*=392), with partner but living apart (*n*=36), single with no partner (*n*=19), widowed (*n*=0), and not stated (*n*=3). Table 4.2 details the marital status of the participants in each allocation group.

Table 4.2: Marital status

	Married/ living with partner	With partner, living apart	Single, no partner	Not stated	**Total**
Control group 1	65	7	3	0	**75**
Intervention group 1	66	5	3	1	**75**
Intervention group 2	67	4	4	0	**75**
Intervention group 3	64	6	5	0	**75**
Intervention group 4	67	6	1	1	**75**
Control group 2	63	8	3	1	**75**
Total	**392**	**36**	**19**	**3**	**450**

4.1.3 Ethnicity

Ethnicity was categorised as: White (*n*=379), Mixed (*n*=4), Asian (*n*=26), Black (*n*=11), Chinese or other (*n*=14) and not stated (*n*=16). A breakdown of ethnicity within each allocation group is provided in Table 4.3.

Table 4.3: Ethnicity

	White	Mixed	Asian	Black	Chinese	Not stated	**Total**
Control group 1	65	0	2	1	4	3	**75**
Intervention group 1	61	0	5	3	2	4	**75**
Intervention group 2	65	0	2	2	2	4	**75**
Intervention group 3	65	1	6	1	1	1	**75**
Intervention group 4	63	2	3	1	3	3	**75**
Control group 2	60	1	8	3	2	1	**75**
Total	**379**	**4**	**26**	**11**	**14**	**16**	**450**

4.1.4 Household income

Household income was grouped into: below £5,000 (*n*=42), up to £10,000 (*n*=22), up to £15,000 (*n*=35), up to £20,000 (*n*=47), up to £40,000 (*n*=125), above £40,000 (*n*=158), and not stated (*n*=21). Household income within each allocation group is recorded in Table 4.4.

Table 4.4: Household income

	Below £5,000	Up to £10,000	Up to £15,000	Up to £20,000	Up to £40,000	Above £40,000	Not stated	**Total**
Control group 1	10	2	8	6	18	27	4	**75**
Intervention group 1	7	4	6	8	19	28	3	**75**
Intervention group 2	10	4	6	9	21	24	1	**75**
Intervention group 3	3	3	6	8	24	29	2	**75**
Intervention group 4	6	6	2	6	19	29	7	**75**
Control group 2	6	3	7	10	24	21	4	**75**
Total	**42**	**22**	**35**	**47**	**125**	**158**	**21**	**450**

4.1.5 Highest level of education attained

Education was recorded by asking participants to report the highest level of education they had obtained, which was: up to age 16 (*n*=45), 16-18 (*n*=62), vocational training (*n*=35), 'A' levels (*n*=67), university (*n*=125), postgraduate (*n*=94), and not stated (*n*=22). Table 4.5 lists highest education level attained for participants by allocation group.

Table 4.5: Highest level of education attained

	Up to age 16	16-18	Vocational training	'A' Level	University	Postgraduate	Not stated	**Total**
Control group 1	8	12	3	11	18	20	3	**75**
Intervention group 1	9	10	4	11	20	18	3	**75**
Intervention group 2	3	17	6	8	21	16	4	**75**
Intervention group 3	6	8	10	12	21	14	4	**75**
Intervention group 4	9	7	8	9	25	12	5	**75**
Control group 2	10	8	4	16	20	14	3	**75**
Total	**45**	**62**	**35**	**67**	**125**	**94**	**22**	**450**

It appears from the socio-demographic data detailed above that each of the allocation groups were comparable in age, ethnicity, marital status, household income and highest level of education attained.

4.2 Drop outs

4.2.1 Ineligible

Out of the 450 participants in the RRCT project 52 dropped out of the NECOT trial because they were no longer eligible. Changes to a participant's status that rendered them ineligible were: gave birth before 37+ weeks gestation (*n*=20), delivered elsewhere to the RVI (*n*=12), had a homebirth (*n*=2), had a miscarriage or an intrauterine death (*n*=2), baby was sent to SCBU (*n*=7), moved away prior to delivery (*n*=1), on medication so cannot breastfeed (*n*=3), and records were closed at the RVI suggesting that they delivered elsewhere (*n*=5).

4.2.2 Withdrawals

There were 24 participants in the RRCT project who withdrew from the NECOT trial for various reasons, such as: did not receive a side-car cot when they were supposed to (*n*=3), not enough time to make the follow-up calls (*n*=1), no reason

given (*n*=17), and changed their mind about breastfeeding their baby and did not want to take part in the study (*n*=3).

4.2.3 Non-compliers

In the NECOT trial analysis will be conducted on the data gathered from the follow-up telephone calls, however where there are gaps in a participant's data of three or more consecutive weeks then the participant's data may not be used. Part of the NECOT procedure is to make three attempts to re-engage participants who have not rang the free-phone automated service for three consecutive weeks; if the participant still does not make any calls, reminder postcards are no longer sent and the participant is classed as a 'non-complier'. In the RRCT project there were 126 participants who were classified as non-compliers with 71 participants who did not engage in the follow-up system and 55 participants who stopped ringing.

Table 4.6 provides a summary of participants who were ineligible, withdrew, and non-compliers (did not engage and stopped ringing) in each allocation group.

Table 4.6: Breakdown of drop outs

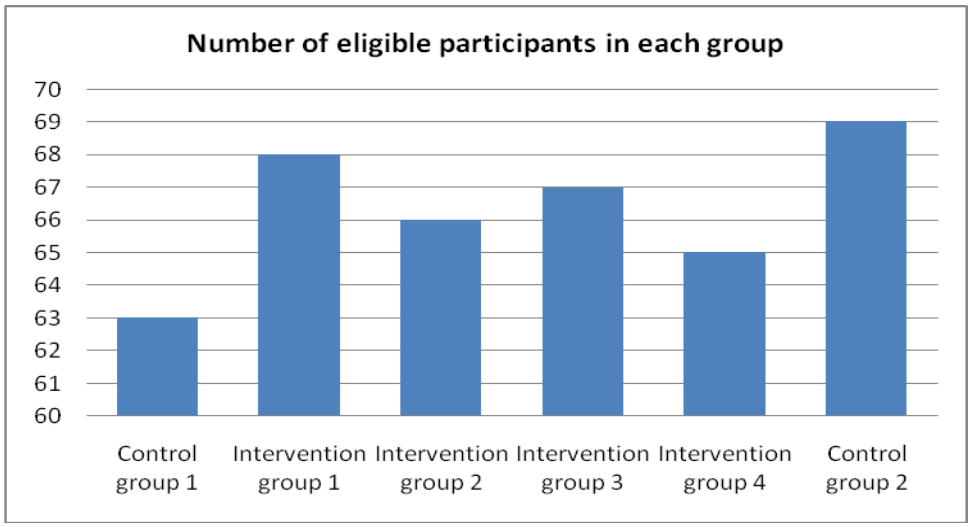
	Ineligible	Withdrawal	Non-compliers (did not engage)	Non-compliers (stopped ringing)	**Total**
Control group 1	12	3	3	13	**31**
Intervention group 1	7	9	14	14	**44**
Intervention group 2	9	3	15	8	**35**
Intervention group 3	8	6	9	5	**28**
Intervention group 4	10	1	18	6	**35**
Control group 2	6	2	12	9	**29**
Total	**52**	**24**	**71**	**55**	**202**

4.3 Analyses

Analyses performed on the effectiveness of each RRCT project intervention compared to the normal procedures adopted by the NECOT trial excluded

participants who did not meet the eligibility criteria. Thus the analyses were performed on the 398 participants still eligible to participate in the NECOT trial after delivery; Graph 4.1 breaks down this figure by RRCT project allocation group.

Graph 4.1: Breakdown of eligible participants by RRCT project allocation group



4.4 Hypotheses testing regarding drop outs

In order to test the hypotheses posed in Chapter 2, Chi-squared tests were conducted looking at completion rates and attrition by comparing a RRCT project intervention group with each RRCT project control group and then against the control groups combined together. Prior to testing the hypotheses Chi-squared tests were conducted to ascertain whether the control groups were different from one another in number of participants who completed the trial compared to the number of participants who did not complete the trial (χ^2 =0.153, degrees of freedom [df herein] =1, p =0.696); no significant relationship was found between retention and being allocated to a particular control group, therefore combining the control groups for analyses was deemed to be justified.

4.4.1 Hypothesis 1: It is expected that there will be a higher attrition rate in the RRCT project control groups compared to the RRCT project intervention groups.

A Chi-squared test was performed on the number of completers versus the number of non-completers for the RRCT project control groups combined compared to the RRCT project intervention groups combined (χ^2 =2.662, df =1, p =0.103).

Hypothesis 1 has to be rejected as the intervention groups combined did not have a significantly higher retention rate compared to the control groups combined.

4.4.2 Hypothesis 2: Participants who receive regular contact with the research team will be less likely to drop out of the NECOT trial.

In intervention group 1, participants received regular newsletters and also a congratulations card and a calendar when they gave birth, therefore this intervention group was used to examine hypothesis 2. The number of people in intervention group 1 who completed and who did not complete the trial was compared to those who completed and who did not complete in control group 1, control group 2 and the control groups combined. This gave the following outcomes: intervention group 1 and control group 1 χ^2 =7.860, df =1 and p =0.005; intervention group 1 and control group 2 χ^2 =6.182, df =1 and p =0.013; intervention group 1 and combined control groups χ^2 =9.587, df =1 and p =0.002.

Therefore testing intervention group 1 with control group 1, control group 2 and the control groups combined, shows there is a significant association between allocation group and trial completion. However hypothesis 2 cannot be accepted as attrition was higher in the intervention group than in either of the control groups, therefore the null hypothesis of 'there is no increase in retention when participants are sent regular newsletters' applies.

4.4.3 Hypothesis 3: The participants who receive both regular contact and a prepaid incentive will have the lowest attrition rate.

Intervention 2 was the same as intervention 1 but in addition participants in intervention group 2 also received a prepaid incentive. A comparison between completers versus non-completers in intervention group 2 against control group 1, control group 2 and the control groups combined tested hypothesis 3 giving the following results: intervention group 2 and control group 1 χ^2 =1.210, df =1 and p =0.271; intervention group 2 and control group 2 χ^2 =0.536, df =1 and p =0.464; intervention group 2 and combined control groups χ^2 =1.120, df =1 and p =0.290.

There was no significant association between retention and intervention 2, therefore the null hypothesis is accepted that is 'there is no difference in retention and drop out rates between those participants who receive both regular contact and a prepaid incentive and those receiving the normal procedures adopted by the NECOT trial'.

4.4.4 Hypothesis 4: Participants who receive their thank you gift when they have given birth (prepaid incentive) will have lower attrition compared to the RRCT project control groups.

Participants in intervention group 3 received their thank you gift as a prepaid incentive. Therefore hypothesis 4 was tested on intervention group 3 and the control groups (separately and combined) looking at the number of participants in each group that completed or did not complete the NECOT trial, and provided the following figures: intervention group 3 and control group 1 χ^2 =0.001, df =1 and p =0.969; intervention group 3 and control group 2 χ^2 =0.191, df =1 and p =0.662; intervention group 3 and combined control groups χ^2 =0.080, df =1 and p =0.777. Thus the null hypothesis of 'drop out rates of participants who receive their thank you gift when they have given birth (prepaid incentive) will not be significantly different to those who received no enhancement' applies.

4.4.5 Hypothesis 5: Receiving free samples before giving birth and being entered into free prize draws after giving birth will have an affect on reducing attrition compared to those participants in the RRCT project control groups.

Intervention 4 was designed to test hypothesis 5 by comparing the number of completers and non-completers in intervention group 4 against the control groups separately and combined. The following results were produced: intervention group 4 and control group 1 χ^2 =0.656, df =1 and p =0.418; intervention group 4 and control group 2 χ^2 =0.189, df =1 and p =0.663; intervention group 4 and combined control groups χ^2 =0.509, df =1 and p =0.475. Thus the null hypothesis of 'receiving free samples and being entered into free prize draws will not have an affect on reducing attrition compared to those participants in the RRCT project control groups' has to be accepted.

Statistical comparison of the RRCT project intervention and control groups indicates that none of the original hypotheses are supported in this study. Potential reasons for this outcome will be discussed in Chapter 5.

4.5 Exploratory analyses regarding trial engagement

Although none of the interventions tested reduced overall attrition it is possible that the interventions produced more subtle effects on participant engagement. In order to investigate this suggestion exploratory (hypothesis generating) analyses were conducted into the effect of the interventions on engagement with the follow-up telephone system.

4.5.1 Number of weeks the participants engaged in the follow-up system

T-tests were used to ascertain whether there was a significant difference between RRCT project intervention and control groups with regards to the number of weeks that participants rang in their data to the follow-up telephone service; the results are listed in Table 4.7. Firstly a t-test was conducted to assess these variables between the two control groups (p =0.467).

Table 4.7: T-tests of engagement of the follow-up procedure

	Control group 1	Control group 2	Control groups combined
Intervention group 1	p =0.001	p =0.012	p =0.001
Intervention group 2	p =0.101	p =0.358	p =0.140
Intervention group 3	p =0.668	p =0.763	p =0.959
Intervention group 4	p =0.307	p =0.770	p =0.460

As with the hypotheses testing significant differences were only apparent between intervention group 1 with control group 1, control group 2 and the control groups combined, with participants in intervention group 1 making the least number of telephone calls to the follow-up telephone system, which would be expected as intervention group 1 had higher attrition.

4.5.2 Intervention effect

The data were analysed (Table 4.8) to ascertain whether there was a surge of re-engagement with the follow-up telephone call procedure after the participants had received an intervention i.e., after receiving newsletter 3, 4 or 5, or after receiving notification of being entered into the three prize draws and/or receiving their prize. Table 4.8 illustrates that intervention 2 which involved providing participants with regular newsletters and a prepaid incentive, and intervention 4 which involved sending free samples and entering participants into free prize draws, were more successful at encouraging re-engagement than intervention 1 which involved sending regular newsletters to the participants and giving a promised incentive.

Table 4.8: Re-engagement after receiving an incentive

	Stopped ringing/did not engage	Number of participants who re-engaged after receiving an intervention	Percentage of participants who re-engaged after receiving an intervention
Intervention group 1	28	4	14.3%
Intervention group 2	23	9	39.1%
Intervention group 4	24	8	33.3%

4.5.3 Reminder telephone calls

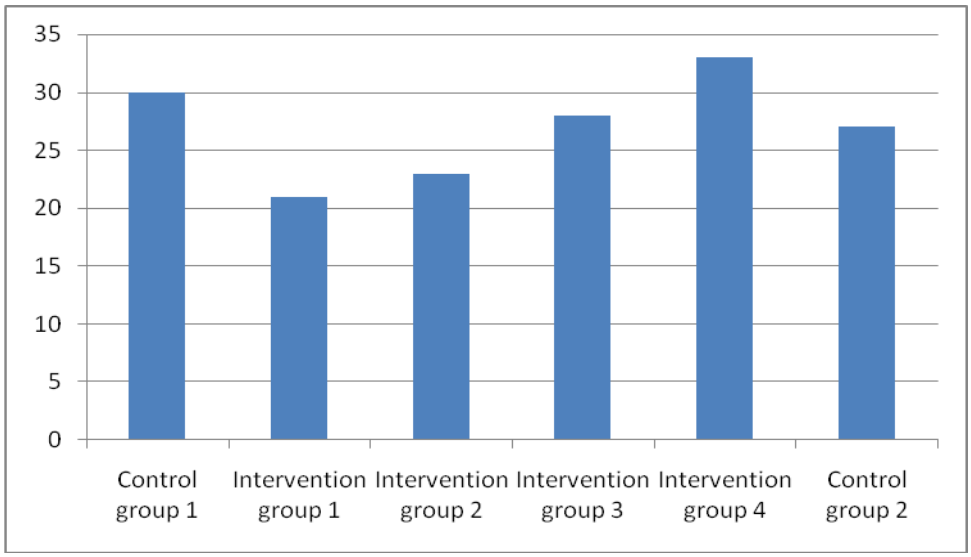
As previously mentioned NECOT participants who failed to ring their data in for three consecutive weeks received a routine reminder telephone call and their missing data were collected over the telephone. Of the 398 eligible RRCT project participants 106 received a reminder telephone call, 18 of which did not complete the NECOT trial; this is summarised by allocation group in Table 4.9.

Table 4.9: Reminder telephone calls

	Received a reminder telephone call	Did not complete the NECOT trial
Control group 1	19	5
Intervention group 1	13	3
Intervention group 2	19	2
Intervention group 3	20	1
Intervention group 4	11	2
Control group 2	24	5
Total	**106**	**18**

It appears that some participants re-engaged with the NECOT trial as a result of receiving a reminder telephone call from a member of the research team. Graph 4.2 records the completion figures by allocation group based on the assumption that these participants would have dropped out of the NECOT trial had they not received a reminder telephone call.

Graph 4.2: Revised completion figures



Chi-squared tests on these figures when comparing the number of completers and non-completers in firstly the RRCT project intervention groups combined against the RRCT project control groups combined and then each intervention group against

the control groups (separately and combined) in order to re-test the hypotheses produced the following data detailed in Table 4.10.

Table 4.10: Hypotheses testing on revised completion figures

	Control group 1			Control group 2			Control groups combined		
	χ^2	df	p =	χ^2	df	p =	χ^2	df	p =
Intervention groups combined							0.503	1	0.478
Intervention group 1	3.853	1	0.050	1.024	1	0.312	2.854	1	0.091
Intervention group 2	2.172	1	0.141	0.265	1	0.607	1.269	1	0.260
Intervention group 3	0.446	1	0.504	0.100	1	0.752	0.035	1	0.851
Intervention group 4	0.127	1	0.722	1.834	1	0.176	1.010	1	0.315

The only significant difference in drop out rates is intervention group 1 and control group 1 suggesting that verbal contact in the form of reminder telephone calls reduced attrition within each allocation group.

4.6 Demographic data

As the literature suggests that participants of low income, low education attainment, ethnic minority, younger cohorts, or single women, are more likely to drop out of a clinical trial, Chi-squared tests or Fisher's exact tests, where applicable, were performed to explore the relationships between these variables in the RRCT study.

4.6.1 Age

Out of the 398 participants eligible to participate in the NECOT trial after giving birth, 12 were aged 18 and under (of which three [25.0%] completed the NECOT study and nine [75.0%] did not), whilst there were 386 participants aged 19 and above (with 246 [63.7%] completing the NECOT study and 140 [36.3%] not completing the study); Fisher's exact test comparing these frequencies produced a p value of 0.007 indicating a significant relationship between age and non-completion. As this sample did not contain many participants aged 18 and under, age was re-categorised to 'Under 25' and '25 or over' for further comparison.

Sixty-eight participants were under 25 and 330 participants were 25 or over, with 21 (30.9%) of those under 25 completing the study whilst 228 (69.1%) of participants 25 and over completed the trial; Chi-squared tests were conducted on the number of participants who either completed or did not complete the NECOT trial based on these age categories and produced the following results: χ^2 =35.143, df =1 and p =0.000. Thus there is a significant association between age and study completion using both cut-off points. A t-test performed on the mean age of completers (32.1) versus the mean age of non-completers (28.7) also confirmed a significant difference (p =0.000).

4.6.2 Marital status

Marital status was grouped into those who lived with a partner/husband (*n*=346) and those living without a partner/husband (*n*=49); three participants did not report their marital status. There were 231 (66.8%) participants living with a partner/husband and 18 (36.7%) participants living without a partner/husband who completed the trial. Analysis comparing completion and non-completion of the NECOT trial depending on marital status returned the following results: χ^2 =16.610, df =1 and p =0.000, showing a significant association with marital status. Marital status could also be a reflection of age as 216/231 of those who lived with a partner/husband and completed the study were 25 or over and 11/18 of those living without a partner/husband and completed the study were 25 or over (χ^2 =21.757, df =1, p =0.000).

4.6.3 Ethnicity

Ethnicity was divided between 'White' (*n*=339) and 'Other' (incorporating Black, Mixed, Asian, Chinese and other) (*n*=46); 13 participants did not report their ethnicity. There were no significant association between ethnicity and trial completion when assessing the number of completers and non-completers on all eligible participants in the NECOT trial; χ^2 =1.143, df =1 and p =0.285, as 219 (64.6%) 'White' and 26 (56.5%) 'Other' completed the trial.

4.6.4 Household income

Household income was re-categorised in two ways: firstly grouped into 'Up to £20,000' (*n*=127) and 'Above £20,000' (*n*=254) with 17 participants not reporting

their household income. Secondly reported household income was re-categorised as 'Up to £40,000' (*n*=244) and 'Above £40,000' (*n*=137). Fifty-one (40.2%) participants with income up to £20,000 completed the trial and 187 (73.6%) participants with income above £20,000 completed the trial and also 127 (52.0%) of those whose household income was up to £40,000 completed the trial and 111 (81.0%) of those whose income was above £40,000 completed the trial. Analyses of the data of household income and number of completers versus non-completers returned the following values: a) where the cut-off point was £20,000 χ^2 = 40.441, df =1 and p =0.000; b) where the cut-off point was £40,000 χ^2 =31.412, df =1 and p =0.000. Thus a significant association was found between household income and trial completion for both cut-off points.

4.6.5 Education

Highest level of education attained was re-categorised in two ways (excluding 20 participants who did not disclose this information). Firstly participants were split between a) 'Up to university' (*n*=188) incorporating education up to 16, 16-18, 'A' levels, and vocational training; and b) 'University' (*n*=190), which included undergraduate and postgraduate education. There was a significant association (χ^2 = 24.785, df =1 and p =0.000) between education and trial completion with 95 (50.5%) of 'Up to university' completing the trial and 143 (75.3%) of 'University' completing the trial.

Education was then split into a) 'Secondary school' (up to 16) (*n*=41) and b) 'Beyond secondary school' (16-18, 'A' levels, vocational training, undergraduate and postgraduate) (*n*=337). Again there was a significant association (χ^2 =13.721, df =1, p =0.000), as 15 (36.6%) of those with the least years of education completed the trial and 223 (66.2%) with 'Beyond secondary school education' completed the trial.

Analyses of the demographic data show that younger cohorts, women living without a partner/husband, women with lower education attainment and women with lower household income are more likely to drop out of a clinical trial. However, ethnicity does not fit the usual trend as there was no significant difference between the ethnic categories 'White' and 'Other'.

4.7 Demographic data – individual categories

Further exploratory analyses of the variables age, marital status, ethnicity, household income and education and whether participants completed the NECOT trial or not were performed to establish whether certain interventions differentially affected specific groups.

4.7.1 Age – 'Under 25' or '25 and over'

There were insufficient data in each group to permit statistical testing of participants aged 18 and under. Therefore testing by Fisher's exact (where a cross-tabulation had an expected frequency of <0.05) or Chi-squared tests were conducted on completion against non-completion of the NECOT trial within each allocation group using the variables of 'Under 25' and '25 and over'. Details of which are listed in Table 4.11.

Table 4.11: Completion figures for 'Under 25' or '25 and over'

	Under 25 Completed	25 and over Completed	Fisher's exact test p =	χ^2	df	p =
Control group 1	3/12 (25.0%)	41/51 (80.4%)	0.000			
Intervention group 1	1/11 (9.1%)	30 /57 (52.6%)		7.047	1	0.008
Intervention group 2	2/12 (16.7%)	38/54 (70.4%)	0.001			
Intervention group 3	4/9 (44.4%)	43/58 (74.1%)	0.065			
Intervention group 4	5/12 (41.7%)	36/53 (67.9%)	0.064			
Control group 2	6/12 (50.0%)	40/57 (70.2%)	0.107			
Control groups combined	9/24 (37.5%)	81/108 (75.0%)		12.729	1	0.000

From the percentages recorded in Table 4.11 both age groups responded to intervention 3 (prepaid incentive); interventions 1 (relationship based intervention) and 2 (combination of interventions) were unimpressive for the under 25s; interventions 1 and 2 had a significantly less impact on the under 25s compared to the participants aged 25 and over.

4.7.2 Marital status –'Living with a partner/husband' or 'Living without a partner/husband'

Chi-squared tests (control groups combined) or Fisher's exact tests (remaining allocation groups) were performed to assess if there were any significant differences between completers and non-completers within each allocation group depending on marital status; details of which are shown in Table 4.12.

Table 4.12: Completion figures for 'Living with a partner/husband' or 'Living without a partner/husband'

	Living with a partner/husband Completed	Living without a partner/husband Completed	Fisher's exact test p =	χ^2	df	p =
Control group 1	42/55 (76.4%)	2/8 (25.0%)	0.007			
Intervention group 1	30/59 (50.8%)	1/8 (12.5%)	0.044			
Intervention group 2	38/59 (64.4%)	2/7 (28.6%)	0.079			
Intervention group 3	41/57 (71.9%)	6/10 (60.0%)	0.210			
Intervention group 4	39/59 (66.1%)	2/5 (40.0%)	0.242			
Control group 2	41/57 (71.9%)	5/11 (45.5%)	0.088			
Control groups combined	83/112 (74.1%)	7/19 (36.8%)		10.491	1	0.001

Significant differences are highlighted between the re-grouped marital status for intervention group 1, control group 1 and control groups combined. The details displayed in Table 4.12 highlight that participants living without a partner/husband were less respondent to intervention 1, where participants received regular newsletters, and those living with a partner/husband were significantly more respondent to intervention 1. Both groups responded to intervention 3 best, which was to give the participants a prepaid incentive.

4.7.3 Ethnicity – 'White' or 'Other'

Assessing the number of completers and non-completers depending on the variables 'White' and 'Other' ethnicity within each allocation group using Fisher's exact tests produced the following data detailed in Table 4.13.

Table 4.13: Completion figures for 'White' or 'Other'

	White Completed	Other Completed	Fisher's exact test p =
Control group 1	40/55 (72.7%)	4/5 (80.0%)	0.398
Intervention group 1	28/55 (50.9%)	3/9 (33.3%)	0.270
Intervention group 2	39/59 (66.1%)	1/6 (16.7%)	0.028
Intervention group 3	40/58 (69.0%)	7/8 (87.5%)	0.208
Intervention group 4	34/54 (63.0%)	4/8 (50.0%)	0.232
Control group 2	38/58 (65.5%)	7/10 (70.0%)	0.276
Control groups combined	78/113 (69.0%)	11/15 (73.3%)	0.227

A significant difference was found in intervention group 2, where participants received regular newsletters and a prepaid incentive, which indicates that this intervention was less effective on 'Other' ethnic groups compared to the ethnic category 'White'.

4.7.4 Income – 'Up to £20,000' or 'Above £20,000'

Association between completion and non-completion figures within each allocation group by income categories 'Up to £20,000' or 'Above £20,000' was examined in more detail by using Chi-squared tests; the results are recorded in Table 4.14.

Table 4.14: Completion figures for 'Up to £20,000' or 'Above £20,000'

	Up to £20,000 Completed	Above £20,000 Completed	χ^2	df	p =
Control group 1	11/23 (47.8%)	30/37 (81.1%)	7.249	1	0.007
Intervention group 1	6/23 (26.1%)	25/42 (59.5%)	6.660	1	0.010
Intervention group 2	7/23 (30.4%)	32/42 (76.2%)	12.964	1	0.000
Intervention group 3	11/19 (57.9%)	36/47 (76.6%)	2.308	1	0.129
Intervention group 4	6/16 (37.5%)	30/43 (69.8%)	5.104	1	0.024
Control group 2	10/23 (43.5%)	34/43 (79.1%)	8.542	1	0.003
Control groups combined	21/46 (45.7%)	64/80 (80.0%)	15.697	1	0.000

Only intervention 3 (prepaid intervention) showed no significant difference suggesting that this intervention had a positive effect on reducing attrition amongst participants whose household income was up to £20,000. Intervention 1 (relationship based intervention) had the lowest response rate overall.

4.7.5 Education – 'Up to university' or 'University'

Due to small frequencies in the category 'Secondary education', statistical testing was only carried out on completion and non-completion for the re-categorisation of education 'Up to university' or 'University'; the results are displayed in Table 4.15.

Table 4.15: Completion figures for 'Up to university' or 'University'

	Up to university Completed	University Completed	χ^2	Df	p =
Control group 1	15/28 (53.6%)	27/32 (84.4%)	6.747	1	0.009
Intervention group 1	12/32 (37.5%)	18/33 (54.5%)	1.899	1	0.168
Intervention group 2	16/30 (53.3%)	23/32 (71.9%)	2.281	1	0.131
Intervention group 3	18/34 (52.9%)	27/30 (90.0%)	10.486	1	0.001
Intervention group 4	16/29 (55.2%)	23/32 (71.9%)	1.841	1	0.175
Control group 2	18/35 (51.4%)	25/31 (80.6%)	6.181	1	0.013
Control groups combined	33/63 (52.4%)	52/63 (82.5%)	13.052	1	0.000

The data in Table 4.15 highlights that intervention 1 (relationship based intervention) was less effective for those who had education up to university level; intervention 3 (prepaid intervention) was most impressive and statistically significant for those who had completed university education.

4.8 Cot allocation

Chi-squared tests were conducted to test the suggestion that participants in the control group of the main trial (NECOT) are more likely to drop out of a RCT. The results from testing completion figures with non-completion figures on the total sample and then by allocation group dependent on NECOT allocation group (side-car cot = intervention, standalone cot = control) is shown in Table 4.16.

Table 4.16: Allocated a side-car cot or a standalone cot

	Side-car cot (intervention) completed	Standalone cot (control) completed	χ^2	df	p =
Total sample	116/197 (58.9%)	133/201 (66.2%)	2.255	1	0.133
Control group 1	20/33 (60.6%)	24/30 (80.0%)	2.806	1	0.094
Intervention group 1	16/34 (47.1%)	15/34 (44.1%)	0.059	1	0.808
Intervention group 2	15/29 (51.7%)	25/37 (67.6%)	1.709	1	0.191
Intervention group 3	21/32 (65.6%)	26/35 (74.3%)	0.599	1	0.439
Intervention group 4	19/31 (61.3%)	22/34 (64.7%)	0.081	1	0.776
Control group 2	25/38 (65.8%)	21/31 (67.7%)	0.029	1	0.864
Control groups combined	45/71 (63.4%)	45/61 (73.8%)	1.633	1	0.201

As can be seen from the results in Table 4.16, there was no significant difference in the total sample between the numbers of completers within the NECOT cot allocation groups. This suggests that in this subset of NECOT participants, attrition was not significantly higher based on NECOT allocation to either the intervention (side-car cot) or control (standalone cot) groups. Also there were no significant differences in number of completers between the NECOT allocation groups within each of the RRCT project allocation groups. Thus suggesting that the RRCT interventions did not have a significant effect on increasing retention of participants depending on whether they were in a NECOT control group or intervention group.

4.9 Summary of the results

In this study none of the original hypotheses were supported and in fact providing a relationship based intervention in the form of newsletters transpired to be significantly less effective than the normal procedures adopted by the NECOT trial (the control groups). The exploratory analyses confirmed findings reported in the literature that women of: younger cohorts, single women, women with low education level attained, and women with low income are more likely to withdraw from a study. Further exploration highlighted that specific interventions appeared to have a positive effect on retention for particular socio-demographic variables. From these findings new hypotheses could be formulated to ascertain whether specific interventions 'encourage' participation from women who are of a younger cohort, living without a partner/husband, have a low education level attained or have a low income, in RCTs. Such hypotheses could be that 'attrition in RCTs amongst younger cohorts of women can be reduced by providing a prepaid incentive'. Similar hypotheses could be postulated for the other socio-demographic variables mentioned above.

Chapter 5: Discussion

The results produced from the various Chi-squared tests, Fisher's exact tests and t-tests conducted on the data gathered from the RRCT project aimed to establish the effect of different interventions on attrition on one third of the sample of participants recruited to the NECOT trial. The RRCT project assessed different types of interventions which previous studies have shown increase retention in RCTs. The RRCT project also considered demographic data within each of the allocation groups and whether participants were allocated to the control group within the NECOT trial as these areas have also been identified in previous studies as reasons for attrition. The aim of the RRCT project was to also apply anthropological theory to these results as an anthropological approach on the subject of attrition and retention in RCTs is absent from the studies and growing body of literature on attrition and retention.

5.1 Study population

Newcastle-upon-Tyne had a total population of 259,536 in 2001 (ONS 2001); population estimates for mid 2008 indicate that there has been an increase in population size to 273,600 (Newcastle City Council 2009). Newcastle-upon-Tyne is composed of 26 wards and characteristics of the population are diverse between the different wards; for example, in the ward of Castle 74.8% of men and 62.9% of women worked, whereas in the ward of West City only 56.5% of men and 46.0% of women were economically active (Ward Fact Card 2001). The economically active figures are reflected in the number of people owning their own property; in Castle 81.1% of people lived in owner occupied housing, whereas in West City 17% of people lived in owner occupied dwellings (*ibid*.). The 2001 records state that the ethnicity of the majority of the population of Newcastle-upon-Tyne was White (British, Irish or Other) (*ibid*.).

A comparison of data relating to some socio-demographic variables was performed to ascertain whether the participants in the RRCT project were representative of the

women who deliver at the Royal Victoria Infirmary (RVI) hospital[4]. The mean age of women who delivered at the RVI between January 2008 and August 2009 was 28.5 (SD 6.17); the mean age of the RRCT project participants was 30.9 (SD 5.74). A t-test was conducted to ascertain whether the age of the RRCT project participants was representative of women who delivered at the RVI. There was unequal variance between these two groups and there was a significant difference in age ($p = 0.000$). The reason for this significant difference could be because an intention to breastfeed is one criterion of the NECOT trial, and breastfeeding rates are highest amongst women aged 30 and above compared to women from younger cohorts (Bolling 2006).

Table 5.1 records the marital status of the women who delivered at the RVI between January 2008 and August 2009.

Table 5.1: Marital status of women who delivered at the RVI between January 2008 and August 2009

	Married/Civil Partnership	Single	Divorced	Separated	Widowed	Not Stated	**Total**
Number of women	4704	4708	51	30	3	893	**10389**

Chi-squared tests comparing the women who delivered at the RVI between January 2008 and August 2009 and the women in the RRCT project, by re-categorising marital status to 'living with a partner/husband' and 'living without a partner/husband' produced values of $\chi^2 = 248.805$, df =1, $p = 0.000$ as 87.1% of RRCT project women were living with a partner/husband and 45.3% of women who delivered at the RVI were living with a partner/husband. This significant difference could be due to the fact that the mean age of women in the RRCT project was higher than that of the women who delivered at the RVI.

Table 5.2 lists the ethnicity of women who delivered at the RVI between January 2008 and August 2009.

[4] All data presented on the women who delivered at the RVI between January 2008 and August 2009 was anonymous and was provided by Lorraine Hobson, Information Manager, The Newcastle Upon Tyne Hospitals NHS Foundation Trust, Department of Information Management, through personal communication on 19 October 2009.

Table 5.2: Ethnicity of women who delivered at the RVI between January 2008 and August 2009

	White	Mixed	Asian	Black	Chinese	Not stated	**Total**
Number of women	7774	75	665	238	480	1157	**10389**

There was no significant difference (χ^2 =3.056, df =1, p =0.080) between the ethnic groups of 'White' and 'Other' between the women who deliver at the RVI and the women who were in the RRCT project, as 84.2% of RRCT project participants were 'White' and 74.8% of women who deliver at the RVI were 'White'. This suggests that the RRCT project participants are representative of the women who deliver at the RVI by ethnicity.

5.2 Methodological issues

It was decided to explore household income by the categories of 'Up to £20,000' and '£20,000 and above' in more detail because the poverty line for a family (couple with two children aged five-14) in the United Kingdom using the 2007/08 figures was £16,744 per annum (Child Poverty Action Group 2009). Therefore it was felt that re-categorising at this cut-off point would mean that all those near the poverty line were included in one category.

Age was split at 25 in the further exploratory analyses as the National statistics for fertility (ONS 2009) show that in 2008 the cohort 20-24 had a similar number of live births in the UK as the cohort 25-29, so it was felt that 25 was a good midway point to split age.

5.3 Hypotheses testing regarding drop outs

As the results indicate none of the original hypotheses were supported by the data obtained here. The number of participants who completed the trial in intervention groups 2, 3 and 4 were similar to the number of participants who completed the trial in both of the control groups suggesting that a combination of relationship based and prepaid incentive, a prepaid incentive and a prize draw/free gift incentive had no significant effect on reducing attrition compared to the effect of the normal protocol adopted by the NECOT trial. It appeared also that the relationship based intervention (intervention 1) had a negative effect on retention rates with a

significantly higher number of drop outs in this group compared to both of the control groups. The reason for this could be that a relationship based intervention in the form of sending regular newsletters, although informative (Hellard *et al*. 2001), may lack the 'personal touch' which can be gained from verbal contact.

5.3.1 Anthropological interpretation of the hypotheses testing

From an anthropological perspective, certain theories can be applied to explain the actions of the participants in response to the interventions tested.

From an evolutionary informed perspective, participants who did not complete the NECOT trial after receiving a prepaid incentive (interventions 2 and 3) or a free sample/prize draw gift (intervention 4) could be said to be Free Riders (Hargreaves Heap and Varoufakis 2004) as they did not contribute to the trial but still claimed the benefit.

Participants who completed the NECOT trial and received a prepaid incentive or free gift (free sample or prize draw) were behaving in accordance with TFT strategy in that receiving these incentives prompted reciprocation in the form of engagement with the follow-up procedure (Axelrod and Hamilton 1981; Hargreaves Heap and Varoufakis 2004).

Participants in the control groups and the relationship based group (intervention 1) who completed the NECOT trial participated for altruistic reasons. That is, they co-operated on the promise of a future reward (£10 thank you gift voucher) (Boyd and Silk 2003; Roberts and Sherratt 1998). The participants who completed the trial and received regular newsletters fulfilled one of Trivers' (1971) requirements of reciprocity in that interaction between researcher and participant occurred often to allow for reciprocation of the act in the form of participation in the follow-up procedure. The reciprocal act was not like-for-like, that is the intervention was met with engagement with the follow-up system (Boyd and Silk 2003), thus co-operation was met with co-operation (Cardwell *et al*. 1999) and the reward was a future one (Stevens and Hauser 2004). That is, co-operation by the research team is an expectation by the participants in response to their co-operation (Pruitt and Kimmel 1977 cited in Dixon-Woods and Tarrant 2009:2216). This is also an

example of moral motivation. These participants could also be said to be following a Prisoner's Dilemma strategy, that is showing trust in their opponent's (the researcher) intentions of providing a future reward (£10 thank you gift voucher) by engaging in the follow-up procedure (Axelrod and Hamilton 1981; Hargreaves Heap and Varoufakis 2004).

From a social anthropological perspective, participants who received a prepaid incentive or a free gift (free sample or prize draw) and did not complete the NECOT trial are an example of negative reciprocity, in that participants are taking the benefit without returning any reciprocity (Sahlins 1972). Participants are also failing to complete their obligation to reciprocate (Mauss [1925] 1967).

Participants who received a prepaid incentive or a free gift (free sample or prize draw) and completed the NECOT trial were displaying behaviour in accordance with building social obligations (Mauss [1925] 1967) and generalised reciprocity (Sahlins 1972). That is the social obligation in accordance to Mauss' ([1925] 1967) rules, is for the participant to accept the item offered - the incentive - and then reciprocate with co-operation by engaging in the follow-up system. For generalised reciprocity to work the reciprocation does not have to be like-for-like (Hendry 1999) as it is a weak obligation with no specific time set for return (Sahlins 1972) therefore receiving an incentive is reciprocated by participants completing the NECOT trial.

Generalised reciprocity can also explain why participants in the control group and relationship based group (with promised £10 thank you gift voucher) completed the NECOT trial as their participation was reciprocated with a £10 thank you gift voucher at the end of their 26 week follow-up period. This could also be viewed as building social obligations whereby the researcher is expected to accept the participants' engagement with the trial and reciprocate with a reward (promised £10 thank you gift voucher).

It could be argued that anthropology is a key discipline in understanding why people participate in a RCT and why some withdraw. Ultimately an anthropological perspective, through this understanding, could assist in reducing attrition from

RCTs. Further exploration of the use of anthropology in reducing attrition could be examined in several ways:

- Recruitment strategies could include applying anthropological theories such as social obligation and moral motivation, into the effect of verbal contact at recruitment. Also at the recruitment stage, examining the effect of notifying potential participants that they will receive a prepaid incentive and/or regular monetary incentives could invoke TFT strategy, Prisoner's Dilemma, reciprocity and social obligations.
- A relationship based intervention that was based on verbal contact between researcher and participant could be tested and moral motivation and social obligations could be evident in this type of scenario.
- An incentive based intervention that involves providing participants with regular guaranteed monetary incentives would examine whether TFT strategy, reciprocity and social obligations were at play and indeed Prisoner's Dilemma.
- Similarly an incentive based intervention that combines a prepaid incentive with regular guaranteed monetary incentives would also test game theory, reciprocity and social obligation.

5.4 Exploratory analyses

T-tests on engagement with the follow-up telephone system were conducted to examine whether there was a relationship between the number of weeks rang and completion of the NECOT trial. The results reflected the findings in the hypotheses testing in that there were significantly fewer weeks of data provided by participants in intervention group 1 (relationship based intervention) compared to the control groups. This was expected as intervention group 1 had higher attrition compared to all the other allocation groups.

Re-engagement in the NECOT trial as a result of receiving an intervention (newsletter or notification of the prize draw and/or receiving the prize) was explored and revealed that receiving the intervention did not have a great effect on retention.

It could be argued that receiving reminder telephone calls had a positive effect on reducing attrition as when the participants who re-engaged in the follow-up system, after receiving a reminder telephone call, were considered as being potential drop outs attrition would have been higher in each intervention and control group. This could be that participants responded to verbal interaction with reciprocity.

5.5 Demographic data

From the demographic data analyses on the total sample, certain patterns arose in line with findings from other studies (e.g., Tough *et al*. 2007; Danoff *et al*. 1994; Areán and Gallagher-Thompson 1996; Ball 2007) thus participants from the younger cohorts, single/living alone, low education attained or lower household income, were significantly more likely to drop out of the NECOT trial. Studies have also shown that participants from minority ethnic groups are more likely to drop out of RCTs (e.g., Tough *et al*. 2007; Danoff *et al*. 1994; Janson *et al*. 2001). However, when ethnicity was analysed according to 'White' and 'Other' ethnic groups there was no significant difference between these groups and the number of people who completed or did not complete the NECOT trial. This could have occurred because one eligibility criterion for the NECOT trial was that participants had to be able to understand English as the follow-up telephone questions were delivered in English. Therefore it is possible that the retention rates by ethnicity are biased due to this factor.

5.6 Demographic data – individual categories

Exploration of the demographic data in more detail made apparent that a relationship based incentive alone was less impressive on all socio-demographic groups that were examined. Out of the interventions tested, intervention 3, whereby participants received a prepaid incentive, appeared to be most effective (except for the category 'Up to university' education whereby the completion rate was 52.9% for intervention 3 but 55.2% for intervention 4 [the prize draw/free sample intervention]). In particular the socio-demographic categories under 25s, living without a partner/husband, other ethnicity and up to £20,000 household income, all had a higher completion rate in intervention group 3 compared to the other intervention groups and the control groups combined. Therefore, it appears that

these groups of people responded to a prepaid incentive, which suggests they are behaving in accordance to TFT game theory and Mauss' social obligations.

Similar results were obtained for the converse of these groups. However participants in the categories: 25 and over, living with a partner/husband, White, household income of over £20,000, and university educated also responded to the combination intervention and free sample/prize. This suggests that participants in these socio-demographic groups were displaying actions that can be explained by TFT, Prisoner's Dilemma, reciprocal altruism, moral motivation, social obligations or generalised reciprocity.

5.7 Cot allocation

It has been reported that control groups tend to attract higher attrition (e.g., Kerr *et al*. 2006; Burns *et al*. 2007) although other studies have recorded no significant difference in attrition between control groups and intervention groups (e.g., Gardiner *et al*. 2005). In the NECOT trial sample studied in the RRCT project there was no significant difference between attrition in the NECOT intervention and control groups. It could be argued that participants in the NECOT control group who completed the NECOT trial participated for the 'greater good' (Aitken *et al*. 2003; Sammons *et al*. 2007; Dixon-Woods and Tarrant 2009; Hayman *et al*. 2001; Janson *et al*. 2001) but without interviewing the participants this can only be assumed. From an anthropological perspective generalised reciprocity, building social obligations, reciprocal altruism and Prisoner's Dilemma can be used to explain the behaviour of participants in the NECOT control group who completed the trial.

5.8 Ethical considerations

Due to the nature of the RRCT project participants had to be blind to the fact that we were attempting to manipulate attrition rates. Additional informed consent was therefore not requested from this subset of the NECOT participants who had already provided informed consent to participate in the NECOT trial. As this was a student project ethical approval was obtained from the Anthropology Department Research Ethics and Data Protection Committee, Durham University.

Originally the incentive based intervention was to be in the format of providing participants with £1.00 lottery scratch cards (Hellard *et al*. 2001) at the intervals stated in Table 3.2, however the researcher was unable to gain ethical approval for this suggestion from the Anthropology Department Research Ethics and Data Protection Committee, Durham University, as the committee felt that providing participants with lottery scratch cards could encourage gambling. Therefore the incentive based intervention was altered on approval by the ethics board.

The RRCT project provided participants with free samples and gifts which were donated by *Tommee Tippee*, *Lansinoh* and *Marks and Spencer*. Participants were made aware that these items were donations and there were no endorsements given from the research team to the items provided in the incentive based intervention.

5.9 Improvements to study design and suggestions for future research

If the RRCT project was to be conducted again, I would suggest changing the relationship based intervention to one that included contact with the participants either over the telephone or face-to-face, due to the effect that the telephone reminder calls appeared to have on retention. Therefore it is possible that contact in this manner may provide a better relationship between researcher and participant as it would be less formal and more intimate. I would also test providing participants with a guaranteed monetary incentive rather than free gifts/prize draws as the participants may not have been aware that they would receive a gift each time and also the gift they received may not have been of benefit to them. Finally, I would consider an intervention that combined a prepaid incentive and regular monetary incentives to further test anthropological theories such as TFT strategy.

5.10 Summary

From these results, anthropological theory can be applied to explain why people participate in and drop out of RCTs. Assumptions can be postulated as to the evolutionary mechanisms that underlay peoples' decision making whereby evolutionary theory and game theory can be applied. Similarly participation and withdrawal from RCTs can be examined by looking at social behaviour, such as generalised reciprocity and building social obligations.

Understanding peoples' decision making from an anthropological perspective can aid researchers in their design and implementation of RCTs. For example if we consider game theory or reciprocal altruism, it could be that the researcher needs to act first by providing an intervention (verbal contact or gift/monetary incentive) for the participant to follow the actions, i.e., co-operation will be met with co-operation. From a social anthropological perspective this could also be the best method used as an obligation for the participant to receive and reciprocate has been created.

Chapter 6: Conclusion

The Retention in Randomised Control Trials (RRCT) project was based on findings of various studies that have examined the use of incentives to increase retention in RCTs. Previous studies have assessed the effect on attrition of relationship based interventions (e.g., Motzer *et al*. 1997; Moore 1997; Gross *et al*. 2001; Hellard *et al*. 2001; Aitken *et al*. 2003; El-Khorazaty *et al*. 2007), incentive based interventions (e.g., Motzer *et al*. 1997; Moore 1997; Cooley *et al*. 2003; Hellard *et al*. 2001; Gross *et al*. 2001), combination of incentives (e.g., Perneger *et al*. 1993; Yammarino *et al*. 1991) and timing of delivering an incentive (e.g., Singer *et al*. 2000; Church 1993). The RRCT project aimed to test various interventions, based on the findings of previous studies, to reduce attrition from the North-East Cot (NECOT) trial.

The RRCT project was unique in that anthropological theories were applied to the results gathered from the study, thus contributing to the growing body of literature on attrition and retention in RCTs. Anthropological theory can play a useful role in designing RCTs as an understanding of the biological and social mechanisms that inform our behaviour and decision making can help in providing interventions that will receive a positive response. For instance researchers could use interventions that invoke behaviour in accordance with TFT strategy, reciprocity and/or social obligations.

Although none of the original hypotheses were substantiated, the exploratory analyses provided some interesting data. Not only, as other studies have shown (e.g., Tough *et al*. 2007; Danoff *et al*. 1994; Areán and Gallagher-Thompson 1996; Ball 2007), was it women from younger cohorts, low education level attained, living without a husband/partner, and low income, who were more likely to drop out of the NECOT trial, but women within these socio-demographic groups were more respondent to the prepaid only incentive. This type of intervention therefore could be utilised and/or modified to elicit high retention from women with any of the above socio-demographic characteristics. A prepaid intervention thus allows for TFT strategy, reciprocity and social obligation to manifest.

The RRCT project provided an opportunity to explore anthropological theory on retention and attrition in RCTs, by testing various interventions against the normal protocol of the NECOT trial. This study could be taken forward by considering biological and social anthropological theories on recruitment strategies, different types of incentive based interventions and relationship based interventions.

Appendix A Newsletters 1 – 5

NECOT NEWSLETTER
ISSUE ONE

North-East Cot Trial

THANK YOU

Thank you for enrolling in the NECOT trial. You should have received a welcome letter telling you that you will shortly get a letter and a sticker with your cot allocation on. Don't forget to put the sticker on the front of the white notes you take with you to the hospital.
If you have any questions about the NECOT trial then either visit our website at:
www.dur.ac.uk/sleep.lab/necot
Or contact us on:
Email: sleep.lab@dur.ac.uk Telephone: 0191 3340351

Profile: Lyn Robinson
Administrator and Recruiter

Lyn studied a Bachelor of Science in Human Sciences (Medical Anthropology) at Durham University, Queen's Campus, Stockton and graduated in June 2007. Currently, Lyn is studying towards a Master of Science by research in Biological Anthropology. Lyn is the Research Coordinator for an up and coming study called the 'Got Milk?' Project, which keeps her busy when she is not recruiting at the RVI or working on administrative duties for the NECOT trial at the Parent-Infant Sleep Lab, Queen's Campus, Stockton.

SUDOKU

		1	5			6		3
8					4			5
	5	9		6	1	4	7	
	4	8	6	5		7	3	
9			4					6
5		7			3	9	2	
	3				6	2		8
			3		8			
6		4	2				1	

(The answer will appear in the next issue)

'GOT MILK?' PROJECT

The 'Got Milk?' Project will look at the timing of the onset of breast milk production for a subset of mothers in the NECOT trial. Mums that take part in this project will be asked to fill in a short home diary, each day from delivery until their baby is 5 days old, and once completed post it back to us. The diaries take no longer than 5 minutes to fill in each day and are easily portable. The 'Got Milk?' Project is looking for 150 NECOT mums to take part so if you are interested or want to know more, please get in touch on the contact details above.

WORDSEARCH

L	B	M	C	N	A	T	A	S	H	A
C	N	O	F	A	L	C	R	N	F	L
H	C	L	F	T	R	H	S	F	J	I
A	N	L	I	A	F	R	L	S	A	C
R	U	Y	O	L	F	R	I	M	Y	E
L	F	R	N	I	L	C	S	E	F	T
O	S	C	A	E	E	Y	E	G	E	A
T	E	G	A	L	L	F	J	A	N	E
T	S	N	A	R	L	S	F	N	R	B
E	J	E	S	S	I	C	A	L	I	E
R	V	A	T	A	E	L	A	U	R	A
A	F	E	L	I	C	I	T	Y	L	S

Find the following words in the grid

ALICE
ANNA
CARRIE
CHARLOTTE
ELLIE
EVE
FELICITY
FIONA
JANE
JESSICA
LAURA
LILLY
MEGAN
MOLLY
NATALIE
NATASHA

Randomized Trials

The point of a randomised trial is to test a new treatment or procedure in the most rigorous way possible. This is done by allocating people to either the normal procedure or the new procedure, which is done at random, and following the outcomes of both groups. There are rules and guidelines for how randomised trials must be run. These rules state that the treatment or procedure being tested must be at least as good as the normal treatment you would receive. The trial must be designed to find out whether the new treatment provides a benefit, and people must suffer no ill effects from taking part. In the NECOT trial the standalone cot is the normal procedure and the side car crib is the new procedure being tested.

Frequently Asked Questions

What happens if I change my address?
Let us know by either emailing or ringing the contacts given above or on the leaflet. Or if you have started ringing the automated phone system then there is also an option to leave us a message at the end of every call.

Will my care be the same if I take part in the trial?
Yes, your care will be the same whether you are in the trial or not and whether your baby is in a standalone cot or a side car crib; your care will not be affected. The only difference will be the cot type you experience on the ward.

NECOT NEWSLETTER
ISSUE TWO

North-East Cot Trial

SUDOKU

		3		4			2	8
	9		3		5		1	
2	6			1		3		
	3		5	8			7	9
	4	1	6			8		
5					2			3
9	1			5	3			7
8			7					5
		7			8	6	4	

(The answer will appear in the next issue)

The Importance of Control Groups

Control groups are an important part of a study. They give us something to compare the tested item against. That is in the NECOT study, having mums in a group who receive the standard cot are so important to the study because the information we get from their phone calls will give us an idea of breastfeeding patterns of mums and babies who receive normal postnatal care. Then we will be able to compare this to the information we get from the phone calls of the mums whose babies had a side car crib. This way we can see whether there is an effect on breastfeeding depending on the type of cot the baby has on the maternity ward. So if you are allocated to a standalone cot, please remember your participation, experience and information are very important, so please phone each week.

Profile: Dawn Mee
Data Manager

Dawn gained her Bachelor of Science in Human Sciences (Biological Anthropology) at Durham University, Queen's Campus, Stockton in June 2007. She is currently studying for a Master of Science by research in Biological Anthropology and her research is connected to the NECOT trial. In 2006 she was part of a team of researchers on a junior research project which looked at whether there is a difference in night time behavioural patterns of mums and babies depending on whether the baby uses a dummy or not. Dawn is the data manager for the NECOT study and she is based at the Parent-Infant Sleep Lab at Queen's Campus, Stockton. Although on occasion she helps with recruiting at the RVI.

WORDSEARCH

A	N	D	R	E	W	L	T	E	A	Y
L	I	A	M	X	S	T	O	L	E	T
E	U	H	A	R	O	K	C	V	J	E
X	B	C	N	C	V	E	R	Y	O	T
A	L	B	S	A	J	A	K	E	S	H
I	C	R	E	T	H	O	N	E	L	E
T	A	A	N	N	A	D	E	U	I	L
S	L	D	A	V	R	A	X	L	R	L
A	L	L	U	M	R	M	R	T	A	I
M	U	E	N	E	Y	A	H	U	M	O
I	M	Y	U	K	H	J	O	S	H	T
U	K	E	T	C	A	L	U	K	E	T

Find the following words in the grid

ANDREW	ELLIOTT	LIAM
ALEX	HARRY	LUKE
BEN	HARVEY	SAM
BRADLEY	JAKE	SCOTT
CALLUM	JOE	
CHARLIE	JOSH	

Answer to the Sudoku in Issue 1

4	7	1	5	9	2	6	8	3
8	2	6	7	3	4	1	9	5
3	5	9	8	6	1	4	7	2
2	4	8	6	5	9	7	3	1
9	1	3	4	2	7	8	5	6
5	6	7	1	8	3	9	2	4
7	3	5	9	1	6	2	4	8
1	9	2	3	4	8	5	6	7
6	8	4	2	7	5	3	1	9

Don't forget our contact details:
Website:
www.dur.ac.uk/sleep.lab/necot
Email: sleep.lab@dur.ac.uk
Telephone: 0191 3340351

Frequently Asked Questions

If my baby is in a side car crib will my bed covers be in the way?
The side car crib is a separate surface to the hospital bed and has its own covers; your bed covers will not cover the side car crib.

What happens if I stop or don't start breastfeeding?
It doesn't matter if something prevents you from starting breastfeeding, or if you do it for just a few days – we still need you to stay in the study and let us know what happens and when, so please still ring on a weekly basis as your answers matter and are part of our study results whether or not you continue to breastfeed.

NECOT NEWSLETTER
ISSUE THREE

North-East Cot Trial

SUDOKU

7			3				5	
	3			9	4		2	8
4	5				8	6		
		1	2				3	6
5	6		4	3			1	
	2				9			7
		7				8		
8	1		7		2		4	9
		3				2		

(The answer will appear in the next issue)

WORDSEARCH

N	E	C	H	T	R	I	B	A	T	M
E	N	E	R	O	T	G	H	O	S	I
C	E	N	I	I	S	S	C	V	T	D
O	W	B	N	R	B	P	S	I	A	W
T	B	A	F	E	R	S	I	C	N	I
T	O	B	I	A	E	D	D	T	D	F
L	R	Y	R	S	A	L	E	O	A	E
B	N	B	M	L	S	C	C	R	L	L
O	O	U	A	G	T	V	A	I	O	S
R	M	Y	R	I	F	Y	R	A	N	C
B	O	B	Y	R	E	T	Y	R	E	R
R	O	T	H	L	D	T	S	M	C	A

Find the following words in the grid

BABY
BOY
BREASTFED
COT
CRIB
GIRL
HOSPITAL
INFIRMARY
MIDWIFE
MUM
NECOT
NEWBORN
ROYAL
SIDECAR
STANDALONE
VICTORIA

The Value of Follow-up Phone Calls

Answering the 4 questions on the automated phone system weekly for 26 weeks is an incredibly important part of the study. This is because this is how we gather the information on breastfeeding patterns of mums and babies and what we will use to compare whether there is a difference in breastfeeding patterns due to the type of cot your baby was given on the maternity ward. So please, please, please ring each week. If you have any problems about ringing the automated phone system or you want us to ring you then just let us know.

Don't forget our contact details
Website:
www.dur.ac.uk/sleep.lab/necot
Email: sleep.lab@dur.ac.uk
Telephone: 0191 3340351

Answer to the Sudoku in Issue 2

1	7	3	9	4	6	5	2	8
4	9	8	3	2	5	7	1	6
2	6	5	8	1	7	3	9	4
6	3	2	5	8	4	1	7	9
7	4	1	6	3	9	8	5	2
5	8	9	1	7	2	4	6	3
9	1	6	4	5	3	2	8	7
8	2	4	7	6	1	9	3	5
3	5	7	2	9	8	6	4	1

Profile: Dr Charlotte Russell
Project Manager

Charlotte was awarded her PhD in Biological Anthropology in June 2007 at Durham University after gaining her BA in Human Sciences also at Durham in 2001. She spent 2 years lecturing in Anthropology at Queen's Campus. Charlotte is the project manager for the NECOT trial. She spends 2 days a week recruiting at the scan clinics at the RVI and the remainder of the week at the Parent-Infant Sleep Lab, Queen's Campus, Stockton, where she deals with the day-to-day management of the NECOT trial.

Frequently Asked Questions

What if I forget to ring on the day I am supposed to ring?
If you forget to ring then as long as you ring within the same week then that is ok. If you forget to ring and a week has passed, then ignore the forgotten week and ring when you get your next week's reminder postcard.

What happens if I go on holiday?
If you go on holiday outside of the UK then just ignore the postcards that arrive whilst you are away. When you come back start ringing again from the next postcard reminder you receive. If you are staying in the UK we could redirect the postcards to where you are staying. If you will be on holiday for more than 2 weeks, please leave us a message on the voicemail so we know when you will be back.

NECOT NEWSLETTER
ISSUE FOUR

North-East Cot Trial

SUDOKU

	4		9		5		1	
	5			4			6	
		8	6		1	4		
		1	3		4	2		
	2			6			5	
	8		1		2		9	
		4		8		5		
3	9						7	2
		6		2		1		

(The answer will appear in the next issue)

Feeding Your Baby

Just so you know it is not part of the study to intervene in any of your feeding decisions or to encourage/discourage you in any way. However, if you stop breastfeeding before your baby is 6 months old, we still need you to phone the automated phone number and answer the 4 questions, as the information you give us is vital and very important to our study.

WORDSEARCH

L	P	A	Y	A	P	P	L	E	A	N
E	A	E	M	S	B	L	N	I	B	E
M	P	S	A	T	S	U	M	A	A	C
O	E	P	N	R	O	M	P	W	N	T
N	K	L	G	R	A	R	E	A	A	A
A	O	I	O	R	N	P	A	C	N	R
W	A	M	W	N	N	A	C	N	A	I
B	B	E	R	I	E	A	H	G	G	N
E	T	P	A	P	A	Y	A	R	A	E
S	T	R	A	W	B	E	R	R	Y	L
A	P	R	N	V	G	Y	E	O	I	F
P	G	P	A	E	O	A	Y	B	N	T

Find the following words in the grid

APPLE	MANGO	PEAR
BANANA	MELON	PLUM
GRAPE	NECTARINE	SATSUMA
KIWI	ORANGE	STRAWBERRY
LEMON	PAPAYA	
LIME	PEACH	

Profile: Catherine Taylor
Administrator and Recruiter

Catherine received her Bachelor of Science in Human Sciences (Medical Anthropology) from Durham University, Queen's Campus, Stockton in June 2007. She is currently enrolled on the Master of Arts in Research Methods in Anthropology at Durham University which will be followed by a PhD research attached to the NECOT study. Catherine is usually at the RVI on a Wednesday talking to and recruiting expectant mums for the NECOT trial.

Answer to the Sudoku in Issue 3

7	8	9	3	2	6	1	5	4
1	3	6	5	9	4	7	2	8
4	5	2	1	7	8	6	9	3
9	7	1	2	8	5	4	3	6
5	6	8	4	3	7	9	1	2
3	2	4	6	1	9	5	8	7
2	4	7	9	5	3	8	6	1
8	1	5	7	6	2	3	4	9
6	9	3	8	4	1	2	7	5

Don't forget our contact details
Website:
www.dur.ac.uk/sleep.lab/necot
Email: sleep.lab@dur.ac.uk
Telephone: 0191 3340351

Frequently Asked Questions

What happens if I stop phoning?
If you don't ring for 3 weeks in a row then a member of the research team will phone you to find out if there are any problems or to see if you haven't rung because you wish to drop out of the study.

What is the benefit from taking part in the study?
The aim of this study is to improve the future maternity care for mothers and their babies, therefore, in the future you yourself or friends and family may benefit from these improvements. Also, don't forget you get a £10 high street gift voucher as a token of our appreciation.

NECOT NEWSLETTER
ISSUE FIVE

North-East Cot Trial

SUDOKU

1			2		7			5
	3						9	
		2	3		4	8		
		4	9		6	3		
	9						7	
3			8		5			2
2		3		4		7		1
			1		2			
4		6		3		5		9

(The answer is below—no cheating)

Thank you

WORDSEARCH

B	R	O	C	C	O	L	I	R	P	S
A	E	L	E	T	T	U	C	E	O	W
R	C	A	R	R	O	T	S	S	T	E
P	A	O	N	I	O	N	A	D	A	D
A	B	R	N	S	P	E	N	R	T	E
R	B	C	I	O	P	O	T	A	T	O
S	A	E	R	C	P	R	U	T	C	I
N	G	L	S	I	R	O	O	T	L	R
I	E	E	N	O	S	I	O	U	E	N
P	R	R	D	U	R	S	A	T	T	E
S	U	Y	F	E	E	C	R	E	S	S
T	C	O	U	R	G	E	T	T	E	H

Find the following words in the grid

BEANS
BROCCOLI
CABBAGE
CARROTS
CAULI
CELERY
COURGETTE
CRESS
LETTUCE
ONION
PARSNIPS
PEAS
POTATO
SPROUTS
SWEDE
TURNIP

Editor's Note

You are now nearing the end of the study with only a few weeks of ringing the automated phone service left. I hope that you have enjoyed receiving these newsletters over the past few months. The whole team would like to thank you for your continued participation in the trial as you have helped contribute towards a valuable piece of research which may benefit mothers in the future. We wish you and your family every happiness for the future and we hope that your baby continues to prosper and bring you many hours of joy. If you have any comments about the newsletter or the trial then please let us know as this will also help us when we are planning future studies. Please keep ringing the automated phone service until your baby is 26 weeks old.
Thank you once again.

The NECOT team.
Email: sleep.lab@dur.ac.uk
Telephone: 0191 3340351

Profile: Dr Helen Ball, Professor of Anthropology Director of the NECOT trial

Helen obtained her PhD in Anthropology at the University of Massachusetts, Amherst in 1991. Her undergraduate degree was in Human Biology, and her interests span both biology and anthropology. For the past 12 years Helen has been involved in studies of infant feeding and sleeping in the North-east of England. Her research has been funded by Foundation for the Study of Infant Death, Babes in Arms, Nuffield Foundation, Leverhulme Trust, Economic and Social Research Council and National Institute for Health research. She has contributed to national guidelines on infant care issued by Royal College of Midwives, UNICEF UK Baby Friendly Initiative, La Leche League, Twins and Multiple Births Association, Multiple Birth Foundation, and the National patient Safety Agency. Helen runs the 'Parent-Infant Sleep Lab' at Durham University's Queen's Campus in Stockton for these studies, and also conducts research in various local hospitals and the community. Helen is the co-chief investigator for the NECOT trial.

Answer to the Sudoku in Issue 4

6	4	2	9	3	5	7	1	8
1	5	7	2	4	8	9	6	3
9	3	8	6	7	1	4	2	5
5	6	1	3	9	4	2	8	7
4	2	9	8	6	7	3	5	1
7	8	3	1	5	2	6	9	4
2	1	4	7	8	9	5	3	6
3	9	5	4	1	6	8	7	2
8	7	6	5	2	3	1	4	9

Answer to the Sudoku in this Issue

1	4	9	2	8	7	6	3	5
8	3	7	6	5	1	2	9	4
6	5	2	3	9	4	8	1	7
7	2	4	9	1	6	3	5	8
5	9	8	4	2	3	1	7	6
3	6	1	8	7	5	9	4	2
2	8	3	5	4	9	7	6	1
9	7	5	1	6	2	4	8	3
4	1	6	7	3	8	5	2	9

Appendix B Congratulations card

Congratulations

on the birth of your baby

With fondest wishes

The NECOT team

Congratulations

NECOT

North-East Cot Trial

Made especially for you by:

dmnecot

Appendix C Calendar

North-East Cot Trial

2008/2009

Don't forget to ring the free phone number on the dates marked

NECOT
Parent-Infant Sleep Lab
Ebsworth Building
Queen's Campus
Durham University
University Boulevard
Thornaby
Stockton on Tees
TS17 6BH

Freepost RRXA-HULZ-HSUG
Parent-Infant Sleep Lab
NECOT
Durham University
Stockton-on-Tees
TS17 6BH

Phone: 0191 3340351

E-mail: sleep.lab@dur.ac.uk

Web address:
www.dur.ac.uk/sleep.lab/necot

May 2008

M	T	W	T	F	S	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

June 2008

M	T	W	T	F	S	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

July 2008

M	T	W	T	F	S	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

August 2008

M	T	W	T	F	S	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

September 2008

M	T	W	T	F	S	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

October 2008

M	T	W	T	F	S	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

November 2008

M	T	W	T	F	S	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

December 2008

M	T	W	T	F	S	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

January 2009

M	T	W	T	F	S	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

February 2009

M	T	W	T	F	S	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	

March 2009

M	T	W	T	F	S	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

April 2009

M	T	W	T	F	S	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

Appendix D Prize draw notification letter

Prize Draw No:

11 August 2008

Dear

I am delighted to announce that Tommee Tippee have offered some of their products in support of the NECOT project. We have decided to allocate these via several prize draws conducted over the course of the project. The first prize draw will take place on **15 September 2008**, and if you have won a prize you will be notified within three weeks of this date. The first prize is a deluxe baby monitor unit and there are 'runners up' prizes of boxes of breast pads. Your prize draw number is printed at the top of this letter. There are no catches involved; we are offering the opportunity to win these donated products simply to thank participants for their involvement in the project. If you prefer not to be involved in the draw then please let us know by **10 September 2008** and we would be happy to remove your name from the list.

Yours sincerely

Dawn Mee
NECOT Research Team

Parent-Infant Sleep Lab, Ebsworth Building, Durham University Queen's Campus, University Boulevard, Thornaby, Stockton-on-Tees, TS17 6BH

Telephone +44 (0) 191 334 0351 Fax +44 (0) 191 334 0249
Email: sleep.lab@durham.ac.uk
www.durham.ac.uk/sleep.lab

Appendix E Prepaid voucher notification letter

19 September 2008

Dear

Congratulations on the birth of your baby. I hope that everything is going well for you all.

You may remember that on the NECOT information leaflet it stated that you would receive a £10 gift voucher to thank you for taking part in the trial. I thought that it may be of more use to you to have your voucher now rather than when you have completed the trial. Therefore I have enclosed your voucher with this letter.

Please remember that you will not receive another voucher at the end of the trial; there is only one voucher per participant.

Please remember to ring the free-phone number each week until your baby is 26 weeks old, as every bit of information we get is very important to our study.

Thank you once again for taking part in the study.

Yours sincerely

Dawn Mee
NECOT Research Team

Voucher Number:

Parent-Infant Sleep Lab, Ebsworth Building, Durham University Queen's Campus, University Boulevard, Thornaby, Stockton-on-Tees, TS17 6BH

Telephone +44 (0) 191 334 0351 Fax +44 (0) 191 334 0249
Email: sleep.lab@durham.ac.uk
www.durham.ac.uk/sleep.lab

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